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Evaluating the TRIPS negotiations: a plea for a substantial review of the Agreement

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The historical context

The successful conduct and conclusion of the TRIPS negotiations can only be understood if they are seen in their historical context.

The late 1980s and early 1990s saw the peaceful disappearance of what seemed like an everlasting East–West confrontation. Then, in the space of a few years, starting with Mr. Gorbachev's tenure in power in the USSR, the autocratic systems were overturned peacefully from within, ending with the disappearance of the USSR itself and the simultaneous appearance of democratically elected governments in the Eastern bloc, for the first time in decades.

This also led to the disappearance of the East–West confrontation by proxy in third countries.

In parallel with this, we witnessed the replacement of autocratic regimes in other countries, especially in Latin America, by democratically elected governments.

No one who has had the privilege of living during that period will forget it. It was as if a window had been opened to let air into a stuffy room, destroying in the process the nightmare of nuclear war. For the first time in nearly half a century, there was a feeling, not that this was "the end of history" but that it was a new beginning, not only for Europe but also for the rest of the world. In Europe, all this coincided with the creation of the single, open market and with the establishment of the political basis for the euro. There seemed to be no limits to what could be done.

Some thought that this was a return to some sort of "normalcy", to the possibility of resolving problems or conflicts through dialogue and negotiation. If only this were still true today ...

I believe that it was this unique political and psychological context that, more than any other factor (of which there were many), created a favourable context for the Uruguay Round of multilateral trade negotiations in general and helped bring about the successful conclusion of the Round and of the TRIPS negotiations. In that sense, we, the negotiators of the Uruguay Round, were translating into binding international obligations the *Zeitgeist* of the early 1990s. This *Zeitgeist* has now disappeared into the mist of history.

The mandate and the objectives

The Uruguay Round, launched in 1986, was the specific context for the negotiations, and was based on the notion of "reciprocal concessions", which were supposed to result in a comprehensive, balanced agreement of sufficient advantage to all. In reality, as any negotiator knows, this objective of a "comprehensive, balanced agreement" is unquantifiable, much more psychological than mercantilist and much more "political" than economically measurable.

At the outset, the aims of trade-related negotiations were expressed in very general terms. This also applied to the TRIPS negotiations:

<u>Trade-related aspects of intellectual property rights, including trade</u> <u>in counterfeit goods:</u>

In order to reduce the distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade, the negotiations shall aim to clarify GATT provisions and elaborate as appropriate new rules and disciplines.

Negotiations shall aim to develop a multilateral framework of principles, rules and disciplines dealing with international trade in counterfeit goods, taking into account work already undertaken in the GATT.

These negotiations shall be without prejudice to other complementary initiatives that may be taken in the World Intellectual Property Organization and elsewhere to deal with these matters.¹

If anything, this is the definition of an open-ended mandate which, depending on the numerous other variables entering into play, could have resulted in a much more modest outcome than the result that materialized after several years of trial and error.

One could, however, say the same about virtually all other aspects of the negotiations. For example, the radical modification of the dispute settlement system does not appear in the very prudent text agreed at Punta del Este.

Is this a lesson for future negotiations? Should one avoid the wordy mandates that often restrict, indeed pre-negotiate, the eventual outcome by circumscribing the negotiations with excessive detail? The question is perhaps not whether one "should" but whether one "could": to return to the argument made at the beginning of this chapter, the atmosphere back then was one, if not of trust, at least of openness to discussion and experiment. Is that the case today? Probably not, but the recurrent theme of this chapter is that we should *try* for this, in the absence of which the multilateral system of the WTO will not evolve to meet the preoccupations of today and tomorrow.

The European context

At the outset, few, if any – certainly on the European side – had a clear idea of what our objectives should be and the European Commission itself, at Punta del Este, was quite reluctant to accept the text reproduced above. Ideas, objectives, and ways and means of expressing our interests, largely "offensive", emerged over time, and our level of ambition grew in step with the understanding that these issues were of major importance for our future and an important element in the overall economic and political equation of the Round. This was, naturally, also influenced by those in the private sector who discovered that here was a process of interest to them.

The European producers of pharmaceuticals were, at the time, the world's biggest investors in research and development (R&D) (and so they have remained, but are now close behind US producers), but their attitude towards the GATT negotiations in general and any TRIPS agreement in particular was hardly one of great enthusiasm, nor was there, initially, much of an interest in other IP-intensive sectors. Their home market was enormous and securely funded by the world's most generous social security systems, access to other developed markets was largely unfettered and exports were significant. Exporting, let alone imposing, European Communities (EC) standards of IP protection to developing countries

was seen as a useful addition to an already healthy profit margin by the pharmaceutical industry, but hardly as a major objective. In any event, there was a general feeling that one should not overdo the level of ambition in respect of these countries – an attitude shared by the EC member states. Without much exaggeration, the basic principle was "live and let live" and this was the reflection of a general attitude towards the development of the "third world" shared by most in European society. Paradoxically – or typically, for the Europeans – there were strong pressures from those with a position of principle to promote without much economic significance, for example, on "moral rights". However, it is also true to say that, when EC industry and other sectors came to understand the extent of the potential agreement as it developed, their support for the negotiations grew exponentially, and the inclusion of the TRIPS Agreement in the WTO became politically essential for the EC.

We were also in the strange situation where relatively little harmonization of IP legislation had taken place at the European level and where the Commission did not have the "exclusive competence" to negotiate externally that it later obtained in a Treaty revision. Consequently, every six months, under each new Presidency of the Council, member states would make solemn declarations to the effect that IP matters were of national, not EC competence, to make sure that the Commission did not forget it ... This has now changed completely and "trade-related IP" issues are firmly anchored in the Treaty as a competence.

Despite these internal complications (which never created any significant problem), from the first to the last day, the EC negotiating positions were led from inside the Commission, aiming at what we thought should become a "reasonable" result for all participants. There were useful contributions made by some member state IP experts and by a a few companies with a strong stake in IP, but these inputs were largely of a general nature. What made our situation different from that of other participants was that pressures exercised by private interests on the negotiators were limited and, in any event, less important than might be the case today, however incredible this may seem to negotiators from other countries.

To an outsider, this may be difficult to grasp, but the EC system was and is such that the Commission is much less directly exposed to external pressures than are its member states, and it is the Commission that negotiates. Member states can, of course, then blame the results on the Commission and they rarely hesitate to do so. The Commission has an obligation to "consult" member states, and it does so having in mind the need to obtain their support at the end of the negotiations. Nevertheless, the involvement of private parties, industry or

non-governmental organizations (NGOs), was far removed from the experience of other negotiators. The internal EC decision-making system was also much less rigid than it is today, without any formal, written negotiating mandate, and with no obligation to submit the results for the acceptance of the European Parliament. I am not arguing that this was "better" than what has emerged through subsequent changes in EC and European Union (EU) treaties and practice, but it worked. For such a system, or "non-system", to work in the public interest, it does, however, require that those in charge are imbued by what they consider to be in that same public interest and capable of promoting it against opposition, internal or external. Many now argue that international negotiations must be conducted much more openly, allowing non-governmental parties to be informed at all stages of the negotiations in order to allow them to intervene to influence the conduct of the negotiations. Right or wrong, this may have undesired or undesirable effects: (i) opening up to pressures from party A by definition also opens to pressures from party B; the relative strengths of the two may lead to an outcome that is not in the public interest, unless you adopt a Darwinian-type interpretation of the latter (i.e. the victory of the strongest); (ii) alternatively, this may lead to a stalemate or defeat the very purpose of the negotiations; (iii) it raises the question of legitimacy: who is "legitimate" to pursue the public interest - democratically elected governments and their representatives or private pressure groups? (The latter will, of course, argue that their governments are wrong and/or have sold out to another pressure group, but from what do they derive their own legitimacy?).

These questions are highly relevant to the question of a possible revision of important parts of the TRIPS Agreement, as suggested below.

One final remark on the European context: 30 years earlier, we had embarked on a unique historical experiment, trying to put behind us 2,000 years of civil war by creating what has become the EU, abolishing age-old barriers and adopting a *de facto* federal approach to most economic legislation. In this process, we hardly made a difference between the opening up to fellow European nationals and to those outside the EC and the whole thrust of this historical experiment was to "transfer competence" (i.e. ever-growing bits and pieces of sovereignty) to "Brussels". Therefore, the notion of abandoning national sovereignty to international bodies became much less of a taboo than in other countries. To some, it became an objective of its own. Many Europeans were therefore enthusiastic "rule globalizers" at that time and quite a few have still not understood that this enthusiasm is hardly shared outside our borders.

North vs South, West vs West?

As the negotiations developed and their aims began to become more clearly defined, at least from the perspective of the *demandeurs* in the industrialized countries, it became increasingly obvious that some developing countries would be asked to make important changes to their IP regimes. However, it would be wrong to imagine that the negotiations were of a classic North–South character. The differences in legal tradition between continental Europe and the United States were such that we must have spent as much time in protracted arguments about the virtues of EC vs US approaches and legal philosophy as we did in "North–South" negotiations. The latter were, in any event, never monolithic. Temporary alliances would be struck between participants on specific issues, without such alliances setting a precedent for cooperating on other issues.

Some believe that the market access concessions dangled in the air by the developed countries helped persuade developing or other developed countries to accept an outcome of the TRIPS negotiations that would require important modifications of their IP regimes. I remember using the argument on occasion, referring mostly to the negotiations on agriculture which, rightly or wrongly, were seen as the holy grail by many developing countries. Did this argument have any real impact? Perhaps, by underlining the general atmosphere of give and take, that this was a global negotiation of interest to all. To suggest that there was a more specific trade-off would be a crude, mercantilist but also unrealistic view of our microcosm. In any event, when a negotiator makes a concession, he or she persuades themselves that it is in their own interest ... If there were any "crude, mercantilist exchanges of concessions", they were very limited and probably more to be found between developed countries. Indeed, in my view, ultimate success was the result of many other factors.

In addition, some of my fellow negotiators from developing countries mentioned during our meeting in February 2015 that they were under pressure of the risk of "unilateral" measures threatened or taken by the United States, in particular with regard to the protection of pharmaceutical inventions. This may or may not have been an important consideration (it obviously was not a concern on the EC side) but it is certainly true that the negotiations on dispute settlement were seen as essential to remove the risk or threat of unilateral action from international trade. This happened as a result of the negotiations on the new dispute settlement system, from my perspective *the* other great achievement of the Uruguay Round.

The "radical" aspects of the new WTO

I have already mentioned the background music of the peaceful revolutions in Eastern Europe and elsewhere and the impression that we were entering a new era of international cooperation (the word "globalization" had not yet become the buzzword it is today), a "return to" and not an "end to" history. Other unquantifiable aspects of the Uruguay Round negotiations were radical in nature, seen as very positive by those who believed in a law-based system for international trade, for example, the creation of the powerful system of dispute settlement referred to above and a reinforcement of agreements in virtually all areas of GATT rule-making (such as trade defence, sanitary and phytosanitary rules, standards, etc.). These were seen as being in the interest of all contracting parties and, if possible, even more so to the advantage of developing countries, supposedly at a disadvantage in terms of defending their interests as compared with the major industrial countries.

What is indisputable is the fact the new GATT, the WTO system, has created the only comprehensive set of rules of virtually universal application, backed up by law and sanctions-based enforcement through the potential withdrawal of "mutual concessions" in the case of non-compliance with the conclusions of the dispute settlement body. The question of the impact of this on "globalization" and the virtues or vices of this phenomenon, is a much broader question, for another symposium.

One last remark on the historical and economic context: these were, generally speaking, years of relative economic optimism. World trade was growing and there were no major crises of the type that one has experienced over the past ten years. There was no mass unemployment in the "West", no financial crisis, no overnight disappearance of whole swathes of industry due to imports.

The atmosphere and conduct of the negotiations, give and take

These are, I believe, the reasons why a group of about 20 or so officials, crammed into various small meeting rooms in the GATT building, could reach agreement on issues that had defied others for many years. Add to this the psychological compatibility of the negotiators and the invaluable contributions made by the Chair of the Negotiating Group, Ambassador Lars Anell, and two exceptionally able and sympathetic staff of the GATT Secretariat, David Hartridge and Adrian Otten. Without their assistance and support, we would not have succeeded.

Mogens Peter Carl

Another reason why the negotiations succeeded was the calibre of the participants, the fact that the negotiators got to know each other, that they engaged in an open debate aimed at persuasion rather than a classic trade negotiation, and that the discussions came to focus on what was seen as "good" or "bad", "persuasive" or "reasonable". Some of us were legal or IP experts. Others, like myself, were professionals otherwise engaged in conducting international economic relations and negotiations. Arguably, the mixture of these two very different professions provided the yeast missing in other fora. This does not, of course, detract from the fact that the delegates from parties with much to gain from increased patent protection (such as the EC) had important economic interests to promote (see also below, on the patent negotiations) but the discussions quickly moved away from the question of "whether" to the question of "how", with what qualifications or restrictions, including the overarching question of compulsory licences.

This was light years away from my experience of other negotiations where the main, if not only, argument was "what will you give me in exchange?" This kind of approach works, and should not be despised, when you are trying to reduce classical trade barriers. It would have been counterproductive in the context of the TRIPS negotiations, and has turned out to be incapable of bringing about agreement in the international climate negotiations.

It could be argued that there was one important conceptual exception in the TRIPS negotiations to the absence of the classic approach of barter or "reciprocal exchange of concessions", at least in conceptual terms. As we all know, or should learn, "more" is not always synonymous with "better". This axiom in certainly true for IP, where public interest requires that the monopoly rights attributed to the owner of IP should be subject to certain exceptions or restrictions, especially in case of abuse, although this naturally applies more to certain types of rights than to others. The recognition of this by the participants put confidence, and political and intellectual flexibility, into the discussions and helped bring about a balanced outcome, in the sense that the interests of users as opposed to those of producers were explicitly, indeed strongly, recognized and protected, at least in some areas. It also took the sting out of a potential North-South disagreement: such public policy considerations are common to all countries; we are almost all both "users" and "producers" of IPRs, taking into account the whole gamut of rights, including not only patents but also copyright, designs, trademarks, geographical indications (GIs) and so on.

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GATT/WTO vs WIPO: WTO+?

This brings us to the thorny question (at the time) of the relation between our work and that of WIPO, which had tried and failed for years to reach agreement on issues of major importance that were finally settled in the GATT/WTO context. What was done in the TRIPS context was a *de facto*, time-limited takeover bid. Whether this takeover bid was "reasonable" or "trade related" or not is now largely beside the point: it happened and it succeeded. Why qualify the words "beside the point" by the adverb "largely"? The reason is that one may ask whether other "trade-related" issues dealt with by other international bodies should be addressed by the WTO. What comes to mind are guestions of labour rights and conditions and questions regarding the protection of the environment and climate, and the impact on and relations between these issues and international trade. This is, of course, of a philosophical and therefore political character: what should be the relative importance attributed to cheap production and imports compared with the conditions of work and life of those engaged in such activities and the future of our physical environment and climate? How many more disasters of the Rana Plaza type (when more than 1,000 workers were killed in the collapse of a garment factory in Bangladesh) will it take before exporters and importers agree to take preventive or remedial concerted action? For me, the limitation of the WTO rulebook to areas that are largely economic is a major weakness in terms of the long-term credibility and success of the WTO system. This view is, however, not shared by most members of the WTO, and the degree of mutual confidence is such that few would be prepared to contemplate negotiations aiming at the inclusion of such issues in the WTO.

Extending the coverage of the WTO system to such other issues is, in the current circumstances, illusory, but then the unexpected can happen when the wheel of history decides to turn. Who would have believed in 1986 that the world would change as rapidly as it did? And who could argue that the world has not changed so much over the past 20 years that a thorough review of the rulebook is becoming overdue?

These negotiations were probably also the last to be conducted and concluded without much publicity or so-called "transparency". Critics might say that this was one of the reasons for the popular backlash, at least by the "anti-globalization" forces, whose violent protests were to accompany international meetings over the coming years. This is, however, doubtful. The TRIPS Agreement changed little in terms of IP protection in the developed countries and the main change for developing countries was arguably positive: the introduction of patent protection

for pharmaceuticals came after a ten-year transition period, leaving substantial time for producers of generics to review their business model. Furthermore, the introduction of legislation fighting trade in counterfeit goods, of which inhabitants in developing countries are the first victims (counterfeit goods kill more citizens in developing than in developed countries). Patent protection for pharmaceuticals was, of course, a very major change but of limited immediate impact post the TRIPS Agreement, if it had not been for the precipitation and excessive greed of certain non-European pharmaceutical producers on the markets of at least two developing countries, South Africa and Brazil. I have always attributed the controversy over "access to drugs" (resolved at Doha in 2001) more to the provocative behaviour of these producers than to the text of the TRIPS Agreement itself. The proof of this lies in the fact that the Doha Declaration on the TRIPS Agreement and Public Health did not call for any amendment to the text of the TRIPS Agreement, except to introduce additional flexibility in terms of compulsory licences for exports. It is also possible that its very adoption led the companies (potentially) tempted to overdo their profit maximization to mind their ways.

The demise of the only post-TRIPS Agreement attempt to agree on additional international rules on IP enforcement, the Anti-Counterfeiting Trade Agreement (ACTA),² was due to much more complex reasons. On the one hand, there was an unusual coalition among major companies with an interest in preserving their dominant position on the Internet and that feared that effective rules would be introduced to combat copyright and trademark infringements essential to their business model; on the other hand, there was a populist backlash against protecting any form of IP, and various NGOs purported to defend access to cheap medicines for patients in poor countries, not to speak of their extraordinary level of incomprehension (more on this below).

A review of the TRIPS Agreement?

All this is relevant to the future of the TRIPS Agreement.

Back in 1990, there was a general consensus that innovation, and its protection, were "a good thing". That consensus is now being battered by the emergence of not only "patent trolls" in the United States but also huge companies that are investing relatively little in R&D and that draw largely on the efforts made by others, which they then translate into assembling very successful consumer products while doing everything possible to minimize the royalties due to the original inventors. The fight against the trade in counterfeit goods or copyright violations

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on the Internet is also assuming a very different dimension and is subject to much less consensus.

No major international negotiation today escapes from public or parliamentary scrutiny or "oversight" by self-appointed critics. This probably implies that negotiations concerning any change to the TRIPS Agreement of any significance would have to be conducted in a very different way. In any event, they would be much more difficult. This would be a pity because any agreement needs to be brought up to date. No agreement is perfect and it would be useful, indeed necessary, to review the substance of the TRIPS Agreement and its pertinence to the world of the twenty-first century, but also the extent to which it is being faithfully implemented by all parties, including some of the major economies.

Five specific issues

Finally, I wish to speak more specifically about five areas of the negotiations, focusing on what I believe was exceptionally important, what went wrong, what has turned out to be insufficient, and therefore also on what should be done now, 20 years subsequently.

1. Copyright

The negotiations on copyright assumed little of the intensity or controversy common to those on patents and GIs. There were relatively few North–South issues, since most developing countries had adopted European-type approaches, but there was more of a confrontation between the United States and the EC over certain specific aspects of copyright protection, such as neighbouring rights and moral rights, where emotions ran high.

What could or should have been the focus of much more discussion was the question of how to protect software. Quite early in the negotiations, there was a lively and friendly discussion between the Europeans and some Latin Americans on the question of whether a specific regime should be envisaged for software (as was the case in France, for example). I was preoccupied by the question because I thought that copyright protection was too absolute, unqualified and without the checks and balances referred to above, and this for something that was increasingly important in economic life. I found, and indeed still find, it unconvincing that the result of an intellectual process in terms of writing a book or a piece of music should be treated in the same manner as the result of another intellectual process such as the creation of software aimed at producing something

which serves an "industrial" purpose. This is not intended to underrate the complexity or intellectual challenge of the latter. The difference, rather, resides in the use and the context of the use of the product of this intellectual process. Software serves an economic purpose and should therefore, in my view, be treated as an industrial invention, through a *sui generis* regime. Such a system should then include the same types of checks and balances that have been created by lawmakers in other areas in order to counteract abuse by right holders.

This general statement needs to be gualified in order to be more precise and practical about the definition of the real, "industrial" problem. Thus, copyright protection only applies if there has been actual (direct or indirect) copying. Also, copyright only protects the actual, detailed expression of an idea or concept, not the idea or concept itself. In other words, even if someone "copies" the general idea or concept of a particular piece of software, but arrives at the same or similar software independently without copying the source code, there is no copyright infringement. So far, so good. The problem, as I understand it, is not with the protection of "software" in the general sense of the term but with the refusal by some right holders to allow access to the source code, such access being indispensable, inter alia, for reasons of interoperability or further development and improvement of proprietary software. If the refusal to allow access to the source code is justified by its owner by invoking copyright, the problem of potentially excessive anti-competitive protection raised in the preceding paragraph becomes real, and of major importance, as demonstrated by a number of major antitrust cases in the EC. The problem may actually be less with copyright protection as such than with the denial of access to the source code. This may, therefore - as has been demonstrated in Europe - be subject to intervention by the competition authorities.

In any event, I found myself in the minority of one, in both the EC and the Negotiating Group, and I therefore regretfully had to drop the attempt to advance the idea of a specific software regime.

Should one envisage a reopening of the question? There seems to be an important problem with respect to the management of the protection of software, especially the source code and access thereto, which may, in any event, be blocked by technical means. The importance of this has expanded manifoldly since the 1990s, accompanied by continued accusations of abuse of dominant position. This should *not* be misunderstood as a plea in favour of the adoption of patent protection for software, but as a plea for an unprejudiced discussion of what is really in the public interest, to the extent that this is still possible in today's very

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different political environment. Is this not the quintessence of a "trade-related" problem?

The question of the protection of copyright and related rights on the Internet has also become of great relevance and of great concern to right holders who find themselves pitted against the interests of the major companies and the insistence on full, unfettered, free-for-all access. In view of the truly globalized nature of the phenomenon, would this not be an area suitable for WTO discussion and action?

2. Patents

The biggest contribution of the TRIPS Agreement towards the adoption of a high, but carefully circumscribed, common level of IP protection was, without any doubt, in the area of patents.

The agreement on patents, five pages in the 1994 collection of legal texts, still reads well today, 20 years later. One could even say that it is a model of relative clarity and economy of words. If negotiated today, it would probably be ten times longer and much less comprehensible.

In a nutshell, what preoccupied the negotiators was how to adopt a quasi-common basis for patent protection, including for pharmaceuticals, while qualifying these rights by a long list of special provisions qualifying and circumscribing these rights, including, in particular, compulsory licences, which came to represent 40 per cent of the total text, but also numerous other issues like exhaustion, patentability and so on.

Once this basic balance had been achieved, the only important variable left, that of time, became the political question that would make or break the negotiations.

Compulsory licences

It would be difficult to over-emphasise the importance of the question of balance between the exclusive rights of the patent owner and the provisions on compulsory licences. Was the balance that emerged from the negotiations right and sufficient? We thought so at the time and it has, to my knowledge, not been questioned since, except in the context of the controversy over "access to medicines" which I believe would never have come about but for the excessive greed of a couple of non-European companies that sought to exploit a specific situation.

The text says in substance that the public authorities may grant exceptions to the exercise of patent rights, for example, if these rights are being abused or if there

is an overriding public interest (e.g. national emergency, extreme urgency). However, and very importantly, the right holder is not deprived of his property: "Due process" is obligatory, and so is an "adequate remuneration".

This is, of course, an extremely condensed summary of the provisions on which we laboured for weeks, in what was a very friendly and intellectually interesting discussion, where many let themselves be pulled into a challenging comparison of arguments of "right" and "wrong".

Has it reached its objectives in terms of ensuring the right balance in terms of protecting private property rights and the public interest?

Partly yes, in those countries where the political and administrative systems are such that the business conduct of private right holders is influenced by the realistic expectation that their rights may be affected by the grant of a compulsory licence if they go too far in terms of exploiting their monopoly rights.

And partly no, in many (most?) other countries with a weaker administrative apparatus. Governments are responsible: it is up to them to implement the TRIPS Agreement in detail, both in terms of undertaking the necessary scrutiny of patent applications and of applying the provisions on "use without authorization" of the right holder.

Has this been done by all governments? Undoubtedly no, and some actors, such as the United Nations Development Programme, argue that even some developing country governments with a high level of administrative capacity (such as that of South Africa) have failed to do so.

Clearly, the TRIPS Agreement cannot be held responsible for imperfect national implementation or inexistent innovation or inefficient public health policies, but it is also a timely reminder of the dangers of drafting and adopting *de facto* international law identical for all parties, regardless of their political and administrative capacities, even if accompanied by the usual references to "special treatment of least-developed countries", if for no other reason that even some advanced developing countries face, and have faced, similar difficulties in implementation.

Balanced texts, drafted in good faith, can only be successfully applied according to the letter and spirit of their authors if those who are supposed to ensure their implementation are willing and capable of doing so. If they are not, the high, but also carefully balanced, level of protection agreed on paper will not be applied in practice. To argue that this becomes a question of "technical assistance", the easy paper panacea for resolving all problems, is not persuasive. In any event, IP protection cannot be separated from the overall emphasis on, and respect for, the rule of law, or lack thereof.

Does this mean that we went too far? More on this below ... but, before that, a few words on "exhaustion", which was hotly debated.

Exhaustion

The main question was whether one could agree on common rules on international exhaustion – a very important issue, especially, but not only, in terms of allowing parallel imports of pharmaceuticals (i.e. unauthorised by right holders). Manufacturers have a clear commercial interest in segmenting markets. Users have a clear interest in the opposite – a classic issue for the GATT/WTO. Suffice it to say that the compromise found was of a Solomonic character: each WTO member may decide on its parallel import regime, provided that it applies the basic GATT/WTO principles of national treatment and most-favoured nation treatment to all right holders.

I still believe that this was the right compromise on this very sensitive political and economic issue. It allows those countries with a predominant "user" interest to adopt international exhaustion, and it allows those with important producer interests to refrain from doing so, if they believe that this would serve to achieve the right balance between domestic producers and consumers.

Another question is, of course, whether the choice is really made on the basis of such a careful examination of what constitutes public interest, but at least this can be done on the basis of a sovereign decision by the governments concerned.

Patentability

The adoption of a universal principle that "patents shall be available for any inventions ... in all fields of technology" (TRIPS Article 27) constitutes the basis for an international community of interest in promoting invention, a belated recognition of the importance of science and technology for our societies. But let us not be hypocritical: it was also of major economic interest to those countries whose industries had a significant interest in promoting universal protection of their inventions.

On the other hand, let us not draw erroneous conclusions from this recognition of self-interest: if one wants to promote and protect R&D, the cost has to be borne

by someone. To me, at least, at the time, it seemed obvious that there would be little privately funded investment in research to develop treatment of tropical or "orphan" diseases unless such investment was supported by the prospect of reaping some return on investment, by definition risky and uncertain. I realise now that this view is not shared by all and that some attribute the lack of investment in combating such diseases to the lack of purchasing power in the less affluent countries. Right or wrong, this was my personal motivation at the time.

Has the adoption of a quasi-universal basis for patent protection had the hoped-for impact on R&D to combat such diseases? It is difficult to find conclusive answers. Some companies have indeed invested, sometimes massively, to find remedies for such diseases. Have they done so because they could expect to receive patent protection for their inventions and recoup their investment or simply because they thought that it was right? Furthermore, some "orphan diseases" may be doubly "orphan" in that they concern such a limited, or poor, population that the cost of developing protection or treatment may be out of proportion to any potential return. In such circumstances, it is up to the public authorities to step in and provide the necessary impetus and financial support. This has begun. Is it enough? Certainly not, yet.

The final compromise

Finally, by the time that the negotiators had reached what they thought was a reasonable balance between qualified monopoly rights and the exercise thereof, some national governments woke up to the fact that there was a risk of their opposition on principle being swept away. Political pressures on negotiators grew by the day from 1991 onwards.

As in many other negotiations, this political problem was resolved by introducing the question of time into the equation. The end result was a mixture of substance and a play of mirrors. In substance, the "statesman-like" decision by India to accept to protect product patents for pharmaceuticals allowed the negotiations to succeed. This was expressed in the TRIPS Agreement as an obligation to "provide as from the date of entry into force of the WTO Agreement a means by which applications for (protection for pharmaceutical inventions) can be filed" and to "apply to these applications, as of the date of application of this Agreement, the criteria for patentability as laid down in this Agreement as if those criteria were being applied on the date of filing … and provide patent protection in accordance with this Agreement as from the filing date in accordance with Article 33 of this

Agreement ..." (note the heavy syntax which, while somewhat inelegant, was very precise).

To an innocent bystander, this looks like gobbledygook. It has to be understood against the background of (i) the existence of a transition period of ten years for the introduction of product patent protection for the countries that wanted it (Art. 65), (ii) the fact that it normally takes about ten years from the start of patent filing to complete the clinical tests and obtain marketing approval in that jurisdiction, by which time only ten years remain to enjoy the associated rights on the market, and (iii) an unsuccessful attempt by certain pharmaceutical lobbies to obtain immediate protection for existing subject matter through "pipeline protection".

The essential elements of the final result were unusually "intelligent" – intelligent not only because of the complexity of the concepts employed and their intricate interrelationship but also because of the unambiguous nature of the result. This also took a lot of courage on behalf of some negotiators, because of the high level of political controversy surrounding the question of patenting medicines, especially, but not only, in India. To their credit, my own political authorities, and European industry, finally accepted and agreed to what I was convinced was a fair deal.

Twenty years after the event, can it be convincingly argued that the interests of developing countries have been prejudiced by the outcome of the negotiations on pharmaceuticals? The contrary is probably the case. At least in some major developing countries, local producers have grown beyond recognition, leaving behind the limited scope of activity of producing generics ("generic" in terms of pre-TRIPS Agreement national law) by copying inventions made elsewhere. This growth has been encouraged by the confidence created by the establishment of an effective level of protection, the great progress made in reliable manufacturing methods, to the point where a substantial proportion of the active ingredients of pharmaceuticals consumed in Europe is now imported from state-of-the-art laboratories located, for example in India.

The main exception to this optimistic conclusion may be the phenomenon mentioned above, the absence of local, national administrative and/or political capability to apply all relevant aspects of the TRIPS Agreement, including its balancing elements, such as compulsory licences. The least-developed countries have been granted several exemptions or transition periods, the latest one being further extended until July 2021. However, if a country with the administrative and political capacity of certain "intermediate" developing countries has difficulties in applying the carefully drafted balance of rights and exceptions, how can one

expect one of the least-developed countries to do so? Would common sense not suggest that at least an additional, substantial transition period be granted to the least-developed countries, falling short of exempting them completely from applying this part of the Agreement? If not, what credible, effective action could be taken to encourage full implementation? Granting a blank cheque, or an overdraft without a time limit, is also unlikely to generate a climate conducive to productive investments – much needed in least-developed countries.

Important problems have, however, emerged in major developed countries and in China. In the United States, the litigation system has allowed the emergence of the destructive phenomenon of "patent trolls" and the previous consensus in favour of those who undertake major R&D efforts is frayed at the edges and made very complex and expensive. As to China, its implementation of the TRIPS Agreement in general and of the patent chapter in particular still leaves much to be desired, because of strategies of favouring "national champions" and a general lack of judicial enforcement – particularly when a foreigner challenges a Chinese company. Do these developments militate in favour of a review of the patent chapter? Perhaps not, with at least one exception, but they do at least suggest that the chapter on enforcement should be substantially strengthened in all relevant respects.

The "one exception" concerns that notion of what constitutes "fair, reasonable and non-discriminatory" (FRAND) terms for licensing IP, especially in the context of international standard-setting. Major disagreements are emerging between key participants and decisions should not be made without a thorough public debate, and international negotiation, of what is in the global interest.

3. Geographical indications

The time and energy spent on discussing GIs was proportionate to the profound disagreement on the very principle of introducing such protection. This was a disagreement that existed not only between Europe (writ large) and Canada, the United States and Australia but also between the EC and a number of other countries to which European emigrants had brought with them the names (but not the *terroirs*) of the places from which they came.

Although economically important, the question was deeply "political" in the sense that the importance attached to protecting GI, or not, assumed the nature of a question of principle, on both sides of the fence.

I could, of course, make the argument for the European approach and position in my sleep, but this is hardly the place for partisan presentations, 20 years after the event. Suffice it to say that the controversy, for the Europeans at least, came to be seen as the fight of the small against the big producers, of traditional methods against industrial processes, even of "good food and drink" against what in French is called *malbouffe* ("junk food" would be the closest translation). To my counterparts, it became a political headache because Europe was trying to obtain a roll-back of existing (ab)uses of European origin appellations, or "usurpations", as we would somewhat poetically refer to them. This would have compelled producers using such names in those countries to abandon their use and adopt other ways of distinguishing their products.

The mixture of a question of basic principle with important commercial interests made the negotiations exceedingly difficult. For those on the other side of the fence, it was, naturally, very difficult to persuade, let alone force, private producers to abandon names that they had been using, sometimes for many years.

The final outcome, which I have just re-read after many years, looks like a sound compromise and was seen as such at the time. In substance, it introduces the principle of protecting GIs in all members of the WTO, defines what this means and then largely "grandfathers" existing use, or misuse as the EU would say, of what are mainly European origin appellations. To my mind, this is a convincing example of a reasonable compromise. It was also seen as the foundation for pursuing an ambition that the EU has subsequently tried to realize, and often succeeded in realizing, in bilateral negotiations, most recently in the free trade area negotiations with Canada.

Ironically, it should also be mentioned that more and more "New World" producers have adopted the concept. Hence, for example, Napa Valley wine producers have registered a GI.

4. Implementation

Has the TRIPS Agreement been implemented by all parties and is it being enforced? The short answer is no.

Days and weeks were spent on the "enforcement" section, which, in terms of WTO-type agreements, is probably a model of comprehensiveness and balance, not to speak of its successful compromise between principles of law enforcement prevalent in continental European civil law and those of the common law tradition.

There are two basic questions that arise in this context: are the basic provisions on substance faithfully implemented by all parties, and are the enforcement provisions, indispensable for the application of the former on the ground, put into effect?

The superficial impression is positive. The great majority of WTO members have put the provisions of the TRIPS Agreement into effect by adopting or adapting national law. Reality is, however, somewhat different.

One could argue that five important problems have emerged:

- As pointed out in the context of the patent protection section above, even advanced developing countries seem to have problems in administering some of the most essential provisions of the patent section, not necessarily to the detriment of the right owners, but to the detriment of their own population.
- Major problems of "real" implementation have been identified in countries such as China that have no tradition of protecting IP, often combined with prejudiced or corrupt law enforcement.
- Other problems have developed over the past two decades, especially in the field of patents, where the emergence of a new profession, that of "patent trolls", was certainly not foreseen at the time (it could, of course, be argued that this problem is not only one of enforcement or administration of rights but rather a problem of the US system of litigation).
- The consensus surrounding the basic principle of IP protection is being battered by the emergence of Internet service providers with opposing interests and other major companies with little investment in R&D and much investment in marketing and lobbying.
- The ever-growing importance of counterfeiting (see also below).

These are questions of major importance to which no answers have yet been found and which the members of the WTO should address, and soon.

5. Trade in counterfeit goods

Trade in counterfeit goods, and its repression, was, at the outset, one of the main objectives of the negotiations: "Negotiations shall aim to develop a multilateral framework of principles, rules and disciplines dealing with international trade in counterfeit goods, taking into account work already undertaken in the GATT."³

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The outcome was an apparently impressive section on border enforcement, which should, of course, be read together with the provisions on enforcement, not to speak of the substantive standards regarding trademarks, copyright and so on.

Why is it, then, that trade in counterfeit goods and other forms of violation of IP rights, for example, on the Internet, have grown exponentially since 1990? Briefly, because the TRIPS Agreement turned out to be a small barrage against an unforeseen tsunami of very powerful interests.

The economic, social and political contexts then were very different from those of today. The Internet was in its infancy, and therefore, by definition, so were violations of rights, especially of trademarks, copyright and related rights. China was not yet a member of the WTO, nor did it occupy the predominant place as a country of origin of counterfeit goods. Twenty or 30 years ago, the use of physical border controls was significantly higher than today. At the European level, there were still physical borders at which goods could be controlled. Today, the EU has become a single entity without internal borders.

The Brave New Globalized World of today makes the fight against counterfeiting much more difficult than when the TRIPS Agreement was drafted, from both the political and a practical perspective: physical border controls have been reduced to a minimum, under pressure from consumers and importers; speedy and lowcost customs procedures have become of the essence. The profits reaped from trade in counterfeit goods have increased immensely, exceeding those derived from drugs trafficking for less risk, with an ever-growing involvement of criminal or even terrorist associations. Trade in counterfeit medicines, pesticides and fertilizers is jeopardizing the health and safety of millions of people. The growth of the Internet and violations of copyright have become virtually institutionalized, the political clout of certain Internet service providers being such that efforts to impose effective controls are being blocked at the level of the public authorities. Add to this a heady mixture of populism, such as the iconic status of a virtually totally unregulated Internet, sheer ignorance of the health impact of counterfeit medicines, and a short-sighted insistence on obtaining the lowest possible price for products at the expense of other objectives. Last, but not least, there has been a decline in the authority of governments, at least in most countries with democratically elected governments, in front of self-appointed "grassroots" NGOs, some of which have intervened in favour of major Internet companies.

Since it soon emerged that the enforcement section of the TRIPS Agreement was clearly insufficient to resolve these problems, a number of countries launched the

ACTA negotiations that led to the adoption of a text that was initialled by the negotiators, but its ratification was subsequently blocked in the EC and the United States, under the pressure of the forces summarized above. It is essential to underline that nothing in the ACTA text changed the substantive balance of the TRIPs Agreement (e.g. there was nothing on patents and *a fortiori* on public health, nothing on duration of copyright protection, etc.). ACTA focused exclusively on the enforcement aspects of commercial-scale violations of the TRIPS Agreement, which could be much improved.

This perpetuates an intolerable situation that, apart from its impact on innovation and creation, puts the lives of millions at risk. One phytosanitary product out of five is counterfeit and/or inherently dangerous. An unknown but also very high proportion of medicines is equally dangerous, even much more so in developing countries, where law enforcement and distribution channel controls are weaker.

This is not the place to propose concrete remedies. There is nothing wrong with the existing provisions of the TRIPS Agreement, but they have clearly become completely insufficient to combat, for example, new channels provided for counterfeiting, such as Internet sales – they represent a small barrage against a huge tsunami. We need a major effort by the WTO members to launch and complete negotiations on an anti-counterfeit treaty that would effectively address these problems, which are the responsibility of all public authorities and the result of a certain *laissez-aller* approach by all – governments, producers, exporters and importers alike.

Conclusions

Ever since the conclusion of the Uruguay Round, there have been attempts to relaunch a comprehensive negotiating process in the WTO. Most of these endeavours have met with failure or have been substantially delayed.

There has been much speculation and discussion surrounding the question of why this has been so. Many have argued that some of the key participants were not willing to accept the necessary compromises and concessions for classic economic reasons, and this remains, apparently, the majority view.

I believe that the reasons are much more fundamental.

First, as argued in the opening paragraphs of this chapter, the Uruguay Round was launched, conducted and concluded in an exceptionally favourable political, intellectual and economic environment. This environment no longer exists.

Second, there has emerged the political and psychological impact of globalization and the social upheaval caused by rapidly expanding international trade, which, by definition, means the reduction or elimination of production and employment in some sectors in some countries, hopefully, but not always, to be compensated by the growth of others.

Third, we have seen the growth of the opposition in many countries to any further international rule-making, perhaps in part as a reaction against the very ambitious outcome of the Uruguay Round. This also explains why most attempts at introducing new areas of rule-making or reviewing existing agreements have met with failure. (The notable, but very partial, exception to this is the Doha Declaration on the TRIPS Agreement and Public Health and the agreement reached in August 2003 to make it easier to export pharmaceuticals covered by a compulsory licence to an importing member that is unable to manufacture the product itself. This happened, however, more than ten years ago).

Fourth, the huge profits made on Internet sales have created a powerful lobby against IP enforcement of both copyright and trademarks. This lobby has been successful in intimidating legislators.

The Doha Round has now largely become focused on classic market access issues. The lack of progress has been presented as a major risk for the WTO system. Nevertheless, the very fact that the rulebook, as adopted in 1994, continues to apply, as witnessed by the dispute settlement system that is being actively used, means that the WTO is still alive and well.

Can this continue? In my view, yes, for several years to come, but rules adopted 20 years ago are beginning to show the signs of age and important gaps have emerged. The mistakes made inevitably by the negotiators, and the strains surrounding the application of certain agreements, all militate in favour of a major review. If this does not eventuate, the WTO agreements will continue, like Snow White, to hibernate until a prince arrives to wake them up. The question is whether that prince will be a harbinger of universal common sense and an understanding of shared interests, or will assume the guise of major upheaval, putting the achievements of the past in jeopardy.

We still have the choice.

Endnotes

- 1 GATT document MIN.DEC, Multilateral Trade Negotiations The Uruguay Round Ministerial Declaration on the Uruguay Round, 20 September 1986.
- 2 ACTA, the 2007–10 attempt to agree on IP enforcement rules. The parties were Australia, Canada, the EC and its member states, Japan, the Republic of Korea, Mexico, Morocco, New Zealand, Singapore, Switzerland and the United States.
- 3 GATT document MIN.DEC.