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EUROPEAN COMMITTEE ON CRIME PROBLEMS
(CDPC)

GROUP OF SPECIALISTS
ON COUNTERFEIT PHARMACEUTICAL PRODUCTS
(PC-S-CP)

Expertise concerning the possible overlapping between existing penal sanctions of violations of IPRs and the future Convention on Pharmaceutical Crime

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Foreword

In this part, the undersigned expert should like to remind the reader of certain peculiarities of high importance with respect to Intellectual Property Rights (IPRs), their possible use and limits.

IPRs include about 10 different types of rights. All these rights have in common that they are exclusive: they do not give the right to do, they give the right to forbid. This exclusive character opens the possibility of obtaining civil damages in case of their violation. The lawmaker has even foreseen, in exceptional cases, to increase the deterrent effect by providing for penal sanctions. Several of these rights, due to their high specialization and to the very nature of the counterfeit types envisaged in the present project (namely counterfeits of medicinal products and medical devices), will in practice never come in consideration for suing this type of counterfeiters.

A precedent preliminary study carried out for the Ad Hoc Group referred to in Chapter I, §11 of the Draft Final Report and consolidated during the CoE Strasbourg Seminar "Counter the Counterfeiters" of 21-23 September 2005 has established that in practice only a few types of IPRs could be engaged against counterfeiters.

First of all, the Trademark rights. These are covering all distinguishing signs (letters, signs, combinations of signs and colours etc.) which can be used in order to designate a marketed medicament or a medical device for it to be distinguished from the other medicaments or medical devices existing on the market. These rights must be registered and last theoretically as long as their owner wishes so, in general as long as the protected designation is commercially exploited and often even longer, if the trademark has acquired a certain public notoriety. These rights are by far the most interesting for counterfeiters to violate, in a form identical to the registered one or in an approaching form capable of deceiving the consumer, since the consumer knows the medicament or the medical device mainly through its trademark right protected trade name.

Secondly, the Patent rights. These are covering essentially technical creations of all kinds. For the sake of the present study, new pharmaceutically active molecules, pharmaceutical compositions, galenic forms, medical devices, processes for their manufacture and use of them are typical examples. Software are not patentable but it is possible to acquire a patent protection on a combination of a medical device incorporating a software especially adapted for its functioning and cooperating with the technical means constituting the device. These rights must also be registered but they have a limited duration, generally of about 20 years (possibly extendable by a few years in advanced countries). Generic medicaments are medicaments for which the patent protection has elapsed. Consequently, counterfeits of generic medicaments cannot be the subject of any civil or penal suit under Patent rights. In addition, for medicaments still protected by patents, particularly dangerous counterfeits - for instance where, in the counterfeit, the active pharmaceutical ingredient (API) is in fact totally absent or present at a sub-standard concentration or has been replaced by another API not encompassed by the patent – cannot be sued under Patent rights as they most of time do not fall under the scope of the claims of the patent which determine the scope of the protection provided by the patent.

Thirdly, the Industrial Model rights. These are covering mainly the aesthetic aspects of a new industrial product, its "design". For the sake of the present study, these rights will very rarely be concerned in connection with medicinal products (although the Viagra pill, characterised by its blue colour and its lozenge form, constitutes an exception) but might play a role for certain medical devices. These rights must also be registered but their duration is even shorter than that of patent rights, around maximum 15 years.

Fourthly, the special rights on Software. These rights are far from existing in every country of the world but they do in most member states of the CoE. They have been created much more recently than the three previously mentioned ones. Their nature is different from one country to another and not yet really harmonised, contrary to the preceding ones. Often, they exhibit a similarity with Copyrights in which they have been sometimes even incorporated. They are not clearly admitted as being part of IPRs. The technical nature of software makes them not well fitted to a traditional protection by Copyright.

In a study carried out for the Ad Hoc group and for a good part included in the Harper report, it could be shown that at least for violations of Trademark and Patent rights, the authors of these violations can often be sued not only before civil courts but also before criminal courts. Of course, very strict conditions must be met in order to trigger criminal suits based on these rights. In particular, wilfulness of the counterfeit as well as an intentional component is indispensable. The sanctions can either be a fine or imprisonment or both. They reach for fines a maximum of the order of 500,000 EUR and for imprisonment of maximum of 8 years, but are in general respectively on average of the order of 10,000 EUR and 1 to 2 years.

Such penalties are – as shown in this study – extremely variable from one Member State of the CoE to another. Some Member States did not even yet have such penalties when the report was established (2004). A similar report (2004), established by the CEIPI for the European Commission and limited to the European Union Member States has also showed that such sanctions are also provided for violations of Industrial Model rights and Software protection rights. They are slightly less severe than for the two others aforementioned rights, on average.

So far, criminal suits are not anchored in the traditional exercise of IP rights. They are very rare. The undersigned is not aware of any penal suit which would have aimed organised criminal infringers of IPRs. However, although the rare cases known so far mainly aimed at repressing recidivist conducts, it is probable that a criminal court referred to by an IPR's owner would not be insensitive to the considerable damage caused to the image of pharmaceutical company when a counterfeit would endanger the health of the consumers. This damage may undermine the "ordre public".

Still, an important aspect is that a criminal suit could only be triggered by the owner of the IPR's right himself. Only then can the Public Prosecutor intervene and possibly add on the criminal penalties that the owner may, for any reason, hesitate to request.

It is reminded that if the owner of an IPR would opt for penal suit, the case would be immediately and temporarily withdrawn from the civil judge to be remitted to the penal jurisdiction. Only after the latter has issued a decision, then financial damages could be obtained. This is one of the reasons why penal sanctions are seldom requested by IPRs' owners. It is clear, however, that in the exceptional circumstances of "wild" counterfeits, the civil aspects will be secondary as the counterfeiter will rarely be solvable. Accordingly, one can expect that IPRs' owner will not hesitate to trigger criminal suits.

Question I: Do Chapters III, IV & V of the draft Final Report go beyond penalisation of violation of IPRs and criminalise offences threatening public health and the health of individuals?

First, concerning the objective defined in Chapter III:

The expert confirms that certain counterfeits types already known to date might totally escape from any suit based on IPRs, hence from any penal sanctions based on IPRs.

Criminal organisations can afford good counsels and will come to the conclusion that their less risky prays will be (i) a generic drug sold under a name (ii) not protected as a registered trademark. In such a criminal counterfeit scenario, IPRs are in the undersigned's opinion totally impotent.

Similarly, if the counterfeiters opt for the attractive enterprise of selling a drug still under patent protection, they can reduce their risk by selling it (1) as a real fake (no patent protected molecule in the dosage, hence no violation of the patent rights) and (2) under a unprotected trade-name, basing all their marketing on the "trivial" name of the API.

For instance, whereas Viagra is a registered protected trademark and was until recently protected also by patent, many consumers were perfectly aware that the API of the "Viagra" is "Sildenafil". Consequently, many offers made on the internet do/did not even mention the protected denomination "Viagra" but only the trivial name "Sildenafil" thereby escaping from the trademark rights protected "Viagra".

With respect to the special behaviour depicted under **§ 25** – a licensed manufacturer producing substandard products – the following should be noticed from the IPR point of view:

(a) It could be that the licensed manufacturer is only beneficiary of a licence of know how, particularly if the medicament is no longer protected by patent. In such a case, as indicated above, intentional or not, the manufacturing of substandard drugs could NOT be sued under an IPR. Probably there would be a breach of the licence agreement but agreements between civil parties can only provide for financial compensations, not for penal sanctions in case of breach of said civil agreement.

(b) If the licensee benefits of a patent licence, the non-respect of the standard qualities likely to have been foreseen in the contract would not amount to a violation of the patent. Hence, whether the production of the low quality product would have been intentional or not will be irrelevant and no civil suit and even less penal suit based on the patent right can be envisaged.

(c) Substandard products sold with a registered trademark the use of which has been legally acquired would not qualify the owner of the trademark right to sue the dishonest licensee under trademark law. At most only a breach of certain obligations of the "book specifications" likely appended to the trademark licence agreement could be recognised.

Whenever in a situation of § 25, a violation of an IPR could be retained against a counterfeiter guilty of commercial misconduct, I do confirm that in any case the criminal intent would be indispensable as a prerequisite to any criminal suit based on said IPR.

Remark: the IPR lawmaker recognises as also constituting an infringement to patent law, the provision of the means allowing an infringement, in so far as this provision was intentional and the provider could not ignore the final infringing destination of the means he was asked to deliver. Thus, the provider of a complex chemical intermediate which is indispensable and can only serve for making a drug protected by patent right, would be regarded as an infringer of these patents as he indisputably knew the final infringing destination of the intermediate. Theoretically, also this provider, not only the counterfeiter himself, could also be sued before criminal court by the owner of the patent rights. The intent, however, would have to be indisputable as the infringement is one of the second degree (the counterfeiter being the first degree). This case is one of those intended under item 11 of the Appendix II to the draft of PC-S-CP.

To summarise on this § 25, licence agreements are in general a conglomerate of very diverse clauses where the IPR licence is surrounded by (one could even say diluted in) numerous clauses of purely commercial or industrial nature. It is hardly conceivable that on the basis of such a contract, a indelicate licensee could be sued before a criminal jurisdiction.

Concerning the scope of future instrument of Chapter IV:

The precise definitions agreed upon in Appendix I **(§ 26)** are perfectly compatible with the items generally objects of trademark and patent rights. They are in no way in contradiction with them and would in no case hinder, limit or increase the exercise of the potentially criminal suit options in connection with these rights. Fundamentally, criminal suits can only be based on indisputable matters and clearly listed activities. Therefore, these definitions would be certainly a useful, clarifying help to the criminal jurisdiction referred to by an IPR owner.

With respect to Appendix II **(§ 27)**, a certain number of behaviours/activities listed under part II thereof certainly extend beyond the behaviours/activities potentially elected to criminal suits based on IPRs: behaviours/activities falling under "4" (partly), "5", "10" and "12" are out of reach of IPRs.

For the others behaviours/activities listed:

- All the activities recited under item "1" of part II would also constitute an infringement to the patent rights (if any exist)
- The same applies to the activities under items "6" to "9" and "11" (when connected to any of the activities "1" and "6" to "9")
- All activities "2", "3" and possibly, in certain cases only, activities "4" could constitute an infringement to trademark law eligible to criminal suits. Activities "6" to "9" and "11" also, provided registered trademarks have been affixed on the products without the consent of the trademark owner

It must be again emphasized that the worst counterfeits (e.g. counterfeits of medicaments containing no patented drug at all) would NOT allow any civil or criminal suit by the owner of the patent right relative to that drug. This imparts a real interest to the repression which could be proposed against authors of activities encompassed under the above mentioned items of Appendix II theoretically (but here practically not) reachable by patent rights.

The limitation referred to in **§ 28** does not exist in IPRs based criminal suit approaches. When referred to by the owner of an IPR, the criminal jurisdiction will only consider the intentional (and serious) commercial "unfairness" of the infringer. The latter can apply to any field, such as also the food, cosmetic or biocide industry.

The fact that an IPR's infringer is a criminal organisation should not necessarily constitute an aggravating factor of penalties in terms of pure Intellectual Property Laws.

The issue mentioned in **§ 29** could only concern patent law. It is presently debated in certain patent offices, particularly in the European Patent Office, whether should be patentable certain processes for screening new drug candidates (by clinical trials) involving in one way or the other (consenting) human subjects (healthy or affected by the targeted disease). The current trend is rather to answer negatively as such processes can be contrary to ethics principle prevailing in Europe. Accordingly, the activities in question would not be repressible through the medium of patent rights. The point made by the Chair is also one precisely put forward by those in favour of patentability of certain such screening methods based on clinical trials as these are more and more outsourced to geographical zones where ethical considerations are much less taken into account than in Europe. Allowing patenting in Europe – under strict limitations – could have a "long arm" impact and a hindering effect abroad.

As a whole, however, "criminal" clinical trials should be considered – in the present state of things - as absolutely out of reach of IPRs based repressive tools.

Concerning Offences referred to under Chapter V:

As already mentioned, criminal suits based on IPRs are rare. Very little case law exists in this respect and it does not appear that any specific feature distinguishes criminal suits based on IPRs from any other criminal suit based on other dispositions of Penal Codes.

Infringing activities are defined very precisely in all IP laws. This is a constant which is due to mainly two facts: (i) the potential criminalisation of the infringements which obliged the lawmaker to define very precisely which commercial or manufacturing activities could bring one in prison and (ii) the remnant approach which prevailed in certain past time period where governments were somewhat hostile to the IP system (hence an historical strict limitation of the activities which were regarded as infringements). It must be borne in mind that IPRs exist in all types of industry and that the present technical field of pharmacy and medicine is only a very small area. However, the repressive provisions of IPRs apply indifferently and in the same way to all fields. Unavoidably, there are on average milder than would seem to be necessary where public security and public health are involved.

With respect to the infringements of IPRs "by negligence" as seems to be debated in **§ 32 & 33**, there is no doubt that such acts, if they would unluckily result in an infringement, could NOT be objects of criminal suits based on IPRs. The criminal intent must be present for bringing such criminal suits to a successful end.

Extradition of criminals as encompassed under **§ 35** is a concept that seems - in the exerciseion of IPRs based criminal suits as observed up to now - totally unrealistic to the undersigned expert . The envisaged Convention would in this respect certainly go beyond the IPRs underlying repressive potential and certainly fulfil an obviously useful complementary repressive tool to IPRs.

With respect to the criminal behaviours/activities listed in **§ 38 to 41**, the following:

- the trafficking of counterfeits referred to in **§ 41** – provided they are protected by IPRs – would be covered by the definition of infringement of IPRs, hence could be repressed, when possible, by them
- the adulteration referred to under **§ 38** would probably not clearly fall under unlawful imitation amounting to an infringement of IPRs, hence could not be repressed criminally through them

- the diversion referred to under **§ 39** could in certain cases fall under certain offences which could be repressed by IPRs due to the territoriality principle attached to the latter. In other word, who would divert goods from a country where he has acquired IPRs to a country where he has none can be an infringer (outside from the E.U.) hence theoretically can be penally sued
- the "tampering" referred to under **§ 40** as already indicated above would be scarcely reachable by patent law – particularly when the tampering is particularly serious hence takes farther from the scope of the patent protection – but could possibly be reachable by trademark law. Such behaviours would traditionally be rather repressed by IP practitioners under "Competition Laws" rather than by exercise of IPRs.

Conclusions:

Notwithstanding the severity of the penalties which could be foreseen in the Convention project, it appears that the measures provided in Chapters III to V would effectively go beyond and would be complementary to the penalties/sanctions which (rarely) could result from the criminal suits possibilities resulting from IPRs.

Questions 2 & 3: Relevance of a possible transposition of Article 10 of the Cybercrime Convention for the present project?

The Cybercrime Convention basically relates to subject-matters which have a possible interface with mainly one type of IPR: Copyright. To a certain extent, also with special laws on Software, hence the expression "Copyright and related rights" used in Article 10.

As indicated in the Foreword, IPRs do not exhibit uniform criminal penalties. There are differences between IPRs and there are also considerable differences between countries. Traditionally, certain countries still have a strong aversion against this type of penalties for IPRs violations.

Copyright is not the IPR where, on average, the toughest criminal penalties are to be found. This is also true for special laws on Software.

The IPRs which could be involved in connection with the medical subject-matters concerned by the present Convention are Trademark, Patent, Industrial Models and Software, in decreasing order of importance.

For the first three of these IPRs, there was little opposition in the European public debate against the general adoption of stronger criminal penalties in case of their violation. More emotions have been noticed for Software laws, where well organised lobbies of free users could make hesitating European governments. For instance, an attempt to let software creations benefiting of the patentability under a revised European Patent Convention aborted in November 2000.

In the European Union, as a consequence of the TRIPS Agreements, considerable efforts for rendering more uniform the civil consequences of violation of IPRs have been made since 1998 and also criminal penalties have been introduced where they did not exist or strengthened. Under the pressure of certain groups, the two aspects have been dissociated as it was feared that criminal penalties could be applied to "minor" (= individuals) infringers of Copyrights and Software. Directive 2004/48/CE of the E.P. and the Council of 29/04/04 consequently only dealt with civil damages. However, it was also recommended that criminal penalties are introduced all over the E.U. in case of infringement made by criminal organisations. A proposal of Directive, COM (2005) 276 of 12/07/2005, provided in its Article 2 for imprisonment of at least 4 years and fines of at least 300,000 EUR in case of IPRs' infringements carried out under the aegis of a criminal organisation and creating a public health or safety risk.

COM (2006) 168 of 26/04/06 provides in its Article 3 for:

"Article 3 – Offences
Member States shall ensure that all intentional infringements of an intellectual property right on a commercial scale, and attempting, aiding or abetting and inciting such infringements, are treated as criminal offences."

In addition, the action for triggering criminal penalties needs not to be initiated by the owner of the IPRs according to this Directive.

Comparable efforts have been made in many other parts of the world in order to introduce criminal penalties for wilful infringements of IPRs, particularly in the most advanced industrialised countries.

It results that, at least for the territory of the E.U., an Article comparable to Article 10 of the Cybercrime Convention does not seem indispensable for most IPRs, in view of the impulse given by the Commission and which should rapidly be followed by adequate legislative measures fulfilling entirely the requirement of Article 10.

In the view of expert, a particular exception, however, should be made for Software referred to under II.3 of Appendix I and which can be used in medical devices as it does not seem to be necessarily the case that Software are encompassed by the above mentioned Directives of the E.U..

An analogous Article may also still make sense – this time with respect to all IPRs - for some of the CoE Member States which are not (yet) part of the E.U. and also if the present Convention is intended to be made open to partners outside from these two territories.

The following Table aims at summarising the expert's opinion:

Opportunity of having an Article similar to Article 10 of the Cybercrime Convention

Country or group of countries / Type of IPR	Patent, Trademark and Industrial Models Rights	Software special Laws
CoE Member States belonging to the E.U.	NO	YES
Certain CoE Member States not in the E.U.	YES	YES
Other Industrially advanced Countries	NO	NO
Certain developing/least developed Countries	YES	YES

When possibly drafting an Article similar to Article 10 of the Cybercrime Convention, assistance can be provided by the Expert. Not all International Conventions mentioned in this Article would fit to Patent, Trademark and Industrial Models Rights.

As already indicated in the preceding answers due to, **the fact that IPRs are often unable to provide an adequate and commensurate penal sanction to wilful counterfeits of the worst type, because a violation of IPRs will often not exist in these cases, it is clear that enough room will be left by an analogue of Article 10 to establish other offences, committed in respect to medical products and endangering public health and the health of individuals.**

Question 4: Are certain illegal and counterfeiting activities harmless on public health and the health of individuals?

First of all, it seems that the present Convention aims at combating criminal organisations. If this is made very clear in the Convention, it will exclude cases when Governments, exercising their right to limit the exercise of certain patent rights interfere with public health. This right to limit patent right is in any case not illegal as will be explained hereinafter.

Secondly, as it has been indicated previously, patent rights will seldom be usable against counterfeits when these are of a particular bad quality, for instance, when no API is contained in the product sold by the counterfeiters.

The expert understands that under the present question only good quality products are meant.

Accordingly, it is necessary to clearly distinguish between "infringement" of patent rights and "counterfeiting" of patented products.

In the first category - **"infringement" -** falls any kind of activity foreseen by patent law which constitutes a violation of patent rights. Infringement is an illegal activity only to the extent that it violates the exclusive right attached to the Patent.

In the second category - **"counterfeiting" -** fall activities which are not only infringements but which are also accompanied by an intentional character, the intent of deceiving the end consumer, and the intent to make money, as much as possible, whilst taking the minimum of risks.

In the case where a government considers that a pharmaceutical product which is still under patent protection, does not come on its domestic market in sufficient quantities or at an affordable price, it may decide to invite the owner of the patent to take measures in order to produce higher quantities, to allow more lawful importations or to decrease the hitherto proposed price.

This problem is solved in most cases by a State-Company negotiation.

However, if the distance between the demands of the State and the maximum commercial effort that the company can consent is too important, <u>legal</u> regulation means do exist.

These are: (i) **the compulsory licence**, (ii) **the expropriation**.

They exist in practically all National patent systems.

(A) The **compulsory licence** is a licence which is forced on the owner of the patent who refuses to produce in a country or does not produce enough or refuses to give a licence to a local producer for producing quantities of goods enough for satisfying the local market.

This type of licence is not favourably considered by big innovative companies which see in it a kind of organised hold-up of the results of their Research efforts.

However, there are two types of compulsory licences.

The first type was spread in the past in certain developing/least developed country but it has now become rare. It could be granted by Law, for any kind of industry and product manufacture, when a local company noticed that there was a domestic market not satisfied by the foreign owner of a patented technique and when the patented technique was not exploited in the country. Negotiation should in principle first have taken place and, if no agreement could be found, the compulsory licence could be requested. This kind of compulsory licence has been heavily criticised and as a whole was probably detrimental to the States which provided for it in their law as their territory was after some years avoided by foreign investors. That was the case of Argentina and too a certain extent of Brazil, in the 70-80ties.

The second type of compulsory licence is nobler in its principle. It can be applied in very limited situations, in particular: (i) when the safety or the military security of a State is threatened, (ii) when there is a nutrition crisis (food shortage) and (iii) when public health is threatened.

Accordingly, only when a medicament is indispensable for treating patients whose life is endangered, a compulsory licence can be envisaged. But it should not be invoked for producing an OTC or "comfort" drugs. The expressions "national emergency" and "extreme urgency" have been used in connection of Anti-HIV drugs. However, the expression "public non-commercial use" has also been included in the TRIPS Agreement which has led to force a compulsory licence on a heart disease drug, Plavix (Thailand). In January 2008, the military-appointed government of Thailand was also advised to issue compulsory licences for 4 anti-cancer drugs.

The mechanism of compulsory licence provides that a State can make a public offer to any company considering itself capable of producing the vital drug in question whilst meeting the price conditions ordered by the State. This company will have to pay an adequate licence fee to the owner of the patent right ("compensation").

This licence is called "compulsory" because it is a licence but it has been imposed to the owner who is forced to find an agreement with the beneficiary of said licence.

Examples of such compulsory licences used to be rare but they always existed. Thus France imposed such a licence to a U.S. antibiotic manufacturer who did not deliver enough antibiotics on the French market just after WWII. In he recent years, many more cases are known in Malaysia, Indonesia, Thailand, Brazil, Argentine and, of course, South Africa, particularly in connection with anti-AIDS drug supply.

Compulsory licences were in general avoided by States in the last 30 years because if they can be forced onto a patent owner once, they have a deterrent effect on investors. The result was in certain countries that no more patent on important drugs were filed and, as a consequence, all the know-how on how to manufacture, purify and formulate them remained inaccessible in these countries. They could have developed it themselves but at such costs in terms of finance and time that they prefer not to choose this forced option. Forcing a patent owner to conclude a licence with an obliged partner does not impose on the owner the obligation to pass to said partner all his know-how concerning this drug (formulation, elimination of impurities, polymorphs stabilisation, etc).

The above depicted situation has changed with the emergence of pharmaceutical companies capable of producing at acceptable quality standards any type of drug, even sophisticated ones, rapidly and at low costs. Typically such companies are spread in India. It is unclear whether they practice dumping prices but it is possibly not the case. The open intent of these companies is to move traditional innovative companies in Europe, North America and Japan out of the World pharmaceutical market.

The TRIPS agreements have ruled the exercise of the right to impose compulsory licences for medicines. The TRIPS agreements are a package of measures where developed and developing/least developed/least developed countries should all have found their advantage. Certain specialists, particularly in the NGOs, consider that the TRIPS provide in other respects many more advantages than drawbacks for developed countries.

According to the TRIPS, the compulsory licences of the second type are possible. They were even admitted not only in the above mentioned situations but also to remedy anti-competitive practices.

Normally, the beneficiary of a compulsory licence should only produce for the need of the domestic market of the country which forced it. Under Article 31f of the TRIPS, the production shall be “predominantly for the supply of the domestic market”. In August 2003, after lengthy debates, a “temporary solution” has been found: no restriction for the exportations to another country with similar needs for an “interim period”. The industrial logic behind is that, in order to produce a drug at low costs, large quantities of it must be manufactured and a domestic market may be insufficient to absorb them.

No need to say that innovative companies are worried by this “temporary solution” which at the beginning of 2007 was still in force as not enough WTO member have ratified the Amendment (WTL/L/641 of 8 December 2005) putting an end to it. In principle, these exportations should be made under the principle of “good faith” which does not seem to create much confidence among patent owners. All the more so that many contradictory projects exist for the extension or the limitation of the TRIPS measures (“TRIPS-plus” going beyond TRIPS measures favourable to developed countries, “A2K” suggesting a safe harbour from certain infringement forms and the introduction of the concept of “compassionate use”).

If as a result of the “temporary solution” owners of pharmaceutical patent rights can locally neither oppose to compulsory licences nor to exportations from compulsory licence granting countries, it remains that since the patent rights are territorial, the patent owners can in principle oppose to the entry of the goods manufactured by a beneficiary of a compulsory licence (licensee) in another country where said licensee does not possess a licence.

In developed industrial countries, there is little doubt that the owner of drug patent will successfully oppose to importation of goods produced abroad under such forced conditions.

In developing/least developed countries, the owner of drug patents might be confronted with considerable antipathies since these countries may be in strong need of these drugs. These countries may in their turn make the choice of granting a compulsory licence on the same drug to such a “compulsory licence based exporter” or to an Indian company.

Going up to the end of the logic, due to the mass effect, a drug invented in Europe could finally be proposed in numerous developing/least developed countries at a price with which the innovative company cannot compete. As a result poor people will be treated at a relatively cheap price. The price to be paid by the countries which host innovative companies may well be, however, a massive loss of research and manufacturing employments. It has also been argued that this situation may be globally advantageous for a majority of citizen of the world in the short term only: investors may be discouraged from investing in pharmaceutical companies which will no longer carry out the extremely costly fundamental research as they were doing for years. It is no sure that States will have enough resources to finance this extremely costly research. It is not sure that Indian companies will be able to do so as well or that Governments of industrial countries will accept to become dependent from foreign industry for producing drugs indispensable for the health of their citizens. It is not sure also that the population and the health care systems of the developed countries will long accept to bear alone the burden of the amortising of innovative companies research costs.

It remains that in principle only one compulsory licence can be (in principle) imposed in a country and that this licence is not exclusive. Accordingly, the owner of the patent rights can still manufacture himself in the country or give a licence to a company other than the beneficiary of the compulsory licence. The expert is not aware of any example where this would have happened. However, similarly to "low cost" airways companies which finally are sometimes owned by major international companies, one could imagine that one day "low cost" pharmaceutical companies will be owned by innovative companies which will compete with "genuine" low cost companies. In Canada, the CAMR is programme organising the acquisition of a compulsory licence for exactly the above purposes.

Another aspect will be mentioned here but not further commented in view of the uncertainty as to its evolution: it is the problem of parallel importations and whether the principle of international exhaustion of (patent) rights will prevail in the future. This could further limit the possibilities – if any - for patent owners to sue "state infringers" also outside from the country where a compulsory licence was imposed.

(B) Another legal possibility, which to the knowledge of the expert was never used so far, is the **expropriation** of the patent owners' right. This uttermost extreme solution could only be envisaged in an extreme emergency situation such as virulent pandemics (e.g. Ebola). It is unlikely to arise although 2 NGOs in Brazil have urged President Lula to envisage it.

In view of the preceding, the expert's answer to Question 4 is that the activities of certain Governments of developing/least developed countries referred to in that question, based on export of goods manufactured under compulsory licences, are at present legal and compatible with patent laws.

These activities will in no case be regarded as "counterfeits" since they are not even "infringements" in the sense of Patent Law. In addition, if the intentional feature which characterizes "counterfeiting" is well present, the intent of deceiving the end consumer is absent if the product manufactured under compulsory licence is of (about) the same quality as that of the genuine drug produced by the innovator.

If, however, the Amendment to Article 31f of the TRIPS agreement would come into force (in principle ratifications should have been taken place before December 2007 but the deadline had to be prolonged until 2009), it is the expert's firm belief that excessive exportations (far beyond what will be considered as necessary to cover domestic needs and to render the manufacturing in the country economically viable) will (i) possibly be regarded as "infringements" in the qualified country ("eligible importing member") where these goods will be exported but (ii) not as "counterfeits" as long as their quality will not deviate from the standards expected for the said drug.

In the expert's opinion, it will be nevertheless important as a precautionary measure to have in the Future Convention a definition of the "pharmaceutical crime" underlining the criminal intent, the criminal character of the activity and defining the concept of "criminal organisation". This will render void any debate on whether "State counterfeits" could possibly exist and probably the best way for eliminating the risk that the Convention could be possibly also regarded as directed to States.