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COMPETITION COMMITTEE

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ANNEX TO THE SUMMARY RECORD OF THE 121st MEETING OF THE COMPETITION COMMITTEE HELD ON 18-19 JUNE 2014

-- Executive Summary of the Discussion on Competition and Generic Pharmaceuticals --

This Executive Summary by the OECD Secretariat contains the key findings from the discussion held during the 121st meeting of the OECD Competition Committee on 18-19 June 2014.

More documents related to this discussion can be found at www.oecd.org/daf/competition/generic-pharmaceuticals-competition.htm

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EXECUTIVE SUMMARY

By the Secretariat[*]

Considering the roundtable discussion and the delegates' written contributions, the following key points emerge:

(1) The existence of originator drugs and innovation by originator companies is vital to develop new treatments against different illnesses and diseases. Following originator innovation, generic substitutes increase competition and result in lower drug prices, which contribute to the reduction of public healthcare expenditure. That is why governments often use a variety of tools to promote generic competition. However, certain regulatory measures may have restrictive effects and should be reformed to promote originator-generic drug competition.

The pharmaceutical industry is an innovative, high-technology and I.P.-sensitive industry that is essential to public healthcare. Originator pharmaceutical companies play an important role by innovating and developing new or more effective treatments. Originators usually count on patent protection to ensure some return on their investments in R&D. At the same time, it is widely recognised that entry by generic pharmaceutical companies enhances competition in the drug markets, driving prices down to the benefit of consumers and governments.

In many countries, prescribed medicines (both originator and generic ones) are to a large extent reimbursed by the public health system. Medicines therefore weigh on the public budget, which is why governments may intervene in the competition process in order to favour cheaper generic substitutes. The level of penetration of generic pharmaceuticals varies substantively across countries, ranging from countries where it is already high to countries where it is still rather low.

The discussion addressed various forms of government intervention and regulations affecting competition between originator and generic drug companies: while some interventions have in fact promoted entry by generic drug companies, others have hindered the competition process and led to a high(er) ratio of originator drug consumption.

Government measures and regulations reported by delegates to enhance originator-generic competition include the following:

- *Reimbursement procedures.* Various countries have eased the administrative procedures for the market entry and reimbursement of generics. In many countries, prescription drugs are reimbursable if they are included on a specific medicine list. So one tool to promote generic competition is to make the listing of generic drugs easier. In some countries conditions are much stringer for originator drugs to be listed and reimbursed than for generic drugs, leading to a very high penetration and consumption of generic pharmaceuticals.

[*] This Executive Summary does not necessarily represent the consensus view of the Competition Committee. It does, however, encapsulate key points from the discussion at the roundtable, the delegates' written submissions, and the Secretariat's background paper.

- *Ingredient-based substitution*. Generic substitution can be promoted through measures at the prescription and/or delivery levels. Various governments require that doctors prescribe medicines on International Non-proprietary Name (that is a collective name for pharmaceuticals containing the same active substance, thus considered to be substitutes) instead of the brand name. Such measures are particularly relevant where pharmacists have to strictly follow the prescriptions. In other countries, pharmacists have been allowed or even required to provide the cheapest version of any prescribed drug – unless substitution is explicitly excluded by the doctor on the prescription.

- *Compulsory licensing*. There is wide recognition of the importance for governments to address public health needs. Countries that face pressing public health situations, e.g. some developing countries may at times consider compelling an originator company to license its patent rights to a generic drug maker. Compulsory licencing provides consumers with earlier and affordable medicine in countries in which a necessary originator drug is not available at an affordable price. At the same time, forcing early generic entry may create uncertainty and disincentives to innovate on the part of originator firms, so these measures should be applied with particular caution.

Other government measures and regulations have had the adverse effect of restricting competition, by raising barriers to entry by generic drug manufacturers:

- *Registration process*. The registration process for market authorisation of generic pharmaceuticals usually require less data, and it is therefore faster and easier than the registration of original medicines. Some jurisdictions, however, do not recognise clinical tests carried out abroad; nor do they admit generic drug applicants to refer to the results of clinical studies carried out for the original medicines. These limitations result in significant delays in the registration process and market entry of new generic drugs.

- *Substitute limitation*. In some countries, the list of authorised generic pharmaceuticals is restrictive and may raise barriers to entry. Where pharmacists are allowed to replace the originator drug with the generic substitute, substitution options are limited if they can only choose from a restrictive list, although other generic substitutes may exist. Such lists may also reduce doctors' and consumers' awareness of the range of available substitutes. In some countries the generics list does not include some frequently used medicines, such as paracetamol and aspirin-based medicines. This contrasts with countries where the lists of authorised generic drugs are more extensive.

Looking ahead, bio-similar medicines may also represent a major competitive pressure in the pharmaceutical sector in respect of biological drugs. Biological drugs are a fast growing industry branch. They are more complex and usually more expensive than the small chemically synthesised molecules, that form the basis of originator drugs and their generic substitutes. Competition authorities have voiced concerns regarding regulations that may restrict bio-similar entry and competition against reference biologic drugs. Such regulations consist notably in restricting the principle of substitutability or therapeutic equivalence of bio-similars, or disproportionate authorisation and registration conditions.

Competition authorities across jurisdictions shall use advocacy to raise the attention of other parts of government on the possible anti-competitive effects of certain measures regulating the pharmaceutical industry. In addition to raising awareness, competition authorities should urge the adoption of regulatory reforms that would eliminate barriers and obstacles to competition in the sector. Experience in some jurisdictions reveal that competition authorities sometimes face resistance from health authorities, despite the substantial public savings that generic drugs may

generate. Competition authorities' co-operation with other agencies (e.g. IP agencies or health authorities) could also provide useful synergies towards effective competition enforcement and advocacy in the pharmaceutical sector.

(2) Competition enforcement plays an important role in preserving and promoting competition to stimulate innovation and reduce prices in pharmaceutical markets. Entry by generic drug companies does not only reduce prices of existing medicines, it also stimulates originator companies to innovate and develop new drugs. The pharmaceutical industry features a number of characteristics that are worthwhile bearing in mind when assessing the conducts of pharmaceutical companies.

The following industry features are worthwhile bearing in mind in assessing pharmaceutical companies' behaviours:

- Regarding the price effects of generic entry, empirical studies show that the price of pharmaceuticals falls moderately upon entry by one generic competitor, and dramatically upon entry by more than one competitor. It generates an obvious incentive for originator companies to try to restrict generic entry in order to keep maximising their profits.
- Assessing the quantitative effects of pharmaceutical companies' strategies is important, too. For most consumer goods, quantities generally rise where prices fall, but this may not be true for pharmaceuticals. Pharmaceuticals are highly regulated products, the principal drug purchaser is the government, and the level of medicine consumption is to a large extent determined by doctors' prescription based on medical conditions. This raises the question as to whether a competition authority should address higher prices for a prolonged period where they might not have appreciable quantitative effects on consumer welfare.
- The pharmaceutical industry heavily relies on patents, which guarantee profits and returns on R&D investments for the originator companies. While the patent holder enjoys a monopolistic power over its patent, that does not necessarily mean market power. In assessing relevant pharmaceutical markets, competition authorities should also consider the heavily regulated environment in which drug makers operate and the fact that switching from a product to another is rarely decided by consumers, rather by doctors and governments.
- Experts have also pointed to the absence of a unified patent enforcement system, and to the difficulty, in many jurisdictions, for originator companies to get adequate compensation for the loss they incur from generic drug companies infringing on their valid patents. Certain practices adopted by originator companies call in question the effectiveness of IP law enforcement mechanisms and the relevance of competition law enforcement in this context.

(3) Antitrust cases against unilateral conducts reveal that originator companies can adopt diverse and creative strategies to delay or prevent generic entry. Such strategies include misuses of the patent system (e.g. ever-greening or patent clustering), spreading misleading information, inducing product switching and refusal to licence an essential patent. Competition enforcement in this context is essential, but it also seems to be sometimes compensating for the failures of the IP and regulatory systems.

Competition authorities and experts have addressed a variety of strategies adopted by originator companies to exclude or delay generic drug competition, such as product hopping, patenting tactics, disinformation tactics, and refusal to give access to essential patents.

Product switching. Product switching cases have proliferated during the last years. At first sight, product switching may seem good as it involves bringing into the market a new, likely more advanced or improved version of an existing drug. This practice starts raising concerns if the new version of the originator drug enjoys stronger, longer lasting patent protection, whereas the older originator drug will soon go off-patent. This may provide an incentive for the originator company to induce a switch by doctors and patients from the original drug to the new one. Such product switch may be induced by the originator company through e.g. promoting the new drug differentially, raising the relative price of the old drug, or withdrawing the old drug from the market. Competition enforcers face the challenge of drawing a line between beneficial innovation and switching strategies that would harm consumers. Recent decisions have found that product hopping amounted to an antitrust violation when the older product was withdrawn from the market. Pharmaceutical companies question, however, how they can keep innovating and improving their products without facing the risk of antitrust enforcement.

Patenting tactics. Ever-greening and patent clustering are two types of patenting tactics raising antitrust concerns. Ever-greening refers to an originator company introducing minor changes to its soon-off-patent medicine (e.g. a slightly different composition) in order to obtain additional or a divisional patent protection, and thereby delay or deter generic entry. Abuse cases establish that seeking additional protection, such as a divisional patent or supplementary protection certificate, is abusive where the sole purpose was to delay generic entry without bringing any new product or development on the market. The question was debated as to whether seeking a divisional patent required that a new or revised product be introduced. Patent clustering (i.e. when an originator company obtains multiple patents covering various aspects of the same product) makes it difficult for potential generic competitors to know for which part of the product and when market entry is possible. As reported by experts, the number of listed patents per drug has increased significantly over the last decades, and most of these patents are not active ingredient patents, but secondary patents.

Caution is required when dealing with the inherent conflicts between competition law and IP rights. It was questioned, in the context of patenting tactics, whether antitrust enforcement is warranted in the use of the regulatory process by companies. Some would rather call for the revision of the patent regulations that allow pharmaceutical companies to obtain patents in such circumstances.

Disinformation tactics. Pharmaceutical companies sometimes intentionally provide false or misleading information to regulators (such as IP agencies), drug providers (hospitals, doctors, pharmacists) or consumers in order to hinder competition or entry of generic substitutes. Disinformation can prove anti-competitive where a pharmaceutical company did not own the patent it claimed, in order to obtain a preliminary injunction against a generic drug competitor. Originator companies can also mislead doctors regarding the quality, efficiency or side-effects of their drugs as opposed to the generic version, to influence doctors' decision and induce them to deny generic substitution. Competition authorities have established that disinformation is anti-competitive where doctors are not knowledgeable enough about medicines to make an independent decision. Others found that there was no competition infringement where doctors had sufficient knowledge and where it was not clear whether the disinformation tactic actually influenced their decisions.

Essential patents. Antitrust claims by generic drug challengers against the refusal by an originator company to license its patent, have generated controversy and important questions: What is an 'essential' patent? Under what conditions does an originator company's refusal amount to an abuse? Who should be entitled to be a licensee? Should refusals rather be addressed through regulatory intervention when it is a matter of public health?

Consumer welfare requires not only cheaper drugs, but also newer and better pharmaceuticals. It is also thanks to the pre-existence of originator drugs that generic substitutes can be developed. The main goal and challenge is therefore to strike the right balance between maintaining high incentives for innovation while promoting the benefits of generic competition. Most abuse cases trigger 'borderline' questions pertaining to IP law enforcement, competition law enforcement and/or regulatory intervention. Competition enforcement appears sometimes to be compensating for the failures of the IP or regulatory systems. Competition authorities should therefore be co-operate with regulators and their advocacy efforts should be encouraged where competition cases reveal that reforms are needed.

(4) Pay-for-delay agreements have attracted increasing antitrust attention around the world. Action has been taken against such agreements where the originator would obtain from the generic drug competitor to delay entry to the detriment of consumers. In addressing pay-for-delay, competition enforcers face key questions pertaining to the applicable legal test, to whether the nature of the patent (i.e. the level of innovation) and the nature and size of payment are relevant in assessing the competition harm.

Pay-for-delay settlements, a.k.a. reverse payment agreements, have captured increased antitrust attention, and competition enforcement actions have been taken on both sides of the Atlantic. Pay-for-delay settlements consist of agreements whereby the originator manufacturer tries to avoid the risk of early generic entry by paying a generic drug company for -delaying the launch of its generic version.

Competition concerns arise where both the originator and generic drug manufacturers benefit from delaying generic entry to the detriment of consumers - that is when the originator company shares its patent revenue with the generic challenger while preventing customers from early access to cheaper generics.

Pay-for-delay agreements have raised a number of debated questions:

- What theory of harm and legal test apply to pay-for-delay: How to distinguish between originator-generic agreements that restrict competition and the ones that may be lawful? Is pay-for-delay restrictive by object, per se, by effect, subject to the rule of reason, or based on other tests or presumptions?

- What sort of "payment" is problematic: Does the nature of the payment matter: cash or other types of advantages or value transfers? Does the size of the payment matter?

- What "delay" is problematic: Where entry is delayed beyond the validity period of the patent or beyond the likely end date of the patent litigation?

- Is pay-for-delay relevant and worrying only in the context of a patent litigation? Is the likely outcome of the patent litigation relevant?

- Is the nature or strength of the originator's patent relevant? Does competition enforcement against pay-for-delay invalidate a patent at stake?

Pay-for-delay occurs where a generic drug company has entered, or threatens to enter the market, while the patent on the originator drug has not expired. This may lead to various types of litigations: e.g. the originator suing the generic company for patent violation (seeking an injunction and compensatory damages) or the generic drug company challenging the validity of

the originator patent in court (seeking to secure its early entry). To avoid the risk of early competition, patent invalidation, or costly and lengthy litigation, the originator company may reach a settlement with the generic challenger. How much the originator would pay, and how long the delay would be for, depend on the bargaining power of the parties and the likely outcome of the litigation they are trying to avoid. Expert statistics show that the strength of the patent plays an important role in the outcome of the litigation: the originator company wins in most cases involving a strong patent, i.e. a primary patent on the active ingredient, whereas the generic challenger is more likely to succeed in case of a weak or secondary patent at stake (e.g. on the formulation or process). Statistics further reveal that most pay-for-delay agreements relate to secondary patents. Competition concerns generally arise if the payment by the originator company delays generic entry later than it would otherwise be.

The regulatory environment – especially IP laws and enforcement mechanisms - also plays a role in pharmaceutical companies' decision to enter into reverse payment agreements. Major differences in the regulatory systems of the EU and the US were identified: in Europe, the IP litigation and enforcement system is highly fragmented and often requires costly and complex patent litigations in multiple jurisdictions. There is limited availability of effective preliminary injunction in the EU, and originator companies virtually never receive adequate compensation for the loss resulting from unlawful generic entry. Also once an originator drug with a valid patent has faced generic entry (even if invalidated), the originator price would rarely reach its initial level back; this drawback may also have a spill-over effect across jurisdictions. This was referred to as 'irreparable harm' by the business and experts. There was a general agreement on the necessity of a unified European patent litigation court to eliminate the current pitfalls. It remains unclear, however, whether and how antitrust enforcement and legal standards take these regulatory burdens into account in assessing originator-generic agreements.

Pay-for-delay has so far been approached as a restrictive horizontal agreement. It remains to be seen whether such agreements could also be caught under abuse of dominance rules, or under merger control. The latter may be particularly relevant where the payment takes place through co-operation or joint activities.

Originator-generic competition can also be hampered by other types of restrictive agreements: competition authorities reported antitrust actions taken against trade association decisions and against horizontal agreements among generic manufacturers, which restricted competition and raised generic drug prices collectively.

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DIRECTORATE FOR FINANCIAL AND ENTERPRISE AFFAIRS
COMPETITION COMMITTEE

ANNEX TO THE SUMMARY RECORD OF THE 121st MEETING OF THE COMPETITION COMMITTEE HELD ON 18-19 JUNE 2014

-- Summary Record of the Discussion on Competition and Generic Pharmaceuticals --

This document prepared by the OECD Secretariat is a detailed summary of the discussion held during the 121st meeting of the OECD Competition Committee on 18-19 June 2014.

More documents related to this discussion can be found at http://www.oecd.org/daf/competition/generic-pharmaceuticals-competition.htm

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SUMMARY OF DISCUSSION

by the Secretariat

The Chair, Frederic Jenny, opened the Roundtable on Generic Pharmaceuticals by noting that the distribution of pharmaceuticals were addressed at the Global Forum of Competition in February, while generic pharmaceuticals were the topic of another roundtable in 2009. The idea of the current roundtable is to identify and discuss more recent issues regarding competition between originator and generic companies and strategies developed by pharmaceutical manufacturers to prevent competition from generics. The 17 highly interesting contributions received to this Roundtable show the importance of the topic.

The Chair introduced the two experts for this roundtable: Professor Scott Hemphill, who is an economist and a lawyer, and a professor at Columbia University; and Mr. Romano Subiotto, competition lawyer at Cleary Gottlieb in Brussels and London. The Chair then introduced the discussion, which would be structured around three themes, together with the most relevant competition questions that these themes raise:

i. The first broader topic would touch on recent developments and regulatory measures affecting generic competition (section I). Under this topic both measures that favour generic firms and regulatory obstacles that hinder competition in the pharmaceutical sector would be addressed. One underlying question here is whether regulatory measures with the effect of lowering drug prices (often by favouring generic competition) have a quantity effect as well. Should competition authorities worry about this phenomenon? Or can it be considered – given that drugs are largely prescribed by doctors based on the medical condition of patients – as a transfer between consumers and pharmaceutical firms with no welfare effects?

ii. The second theme would address anti-competitive practices and antitrust enforcement (section II), further divided into anti-competitive unilateral practices and anti-competitive horizontal agreements. Unilateral practices are usually related to the manipulation of the regulatory process by pharmaceutical companies or misleading e.g. patent authorities. The interesting question here is how to distinguish between manipulation that may or may not be anti-competitive, since it is not always obvious that manipulation of the processes or authorities would necessarily amount to an abuse of dominance or even entail any competition issue. The Chair also pointed out that this relationship between manipulation and anti-competitive practice is more general than pharmaceuticals, referring to the LIBOR manipulation for example. Regarding horizontal agreements, especially pay-for-delay agreements, the following key questions are to be addressed: (1) What is the theory of harm? (2) How to recognise whether it is an anti-competitive practice? (E.g. does it depend on the amount of the transaction? What happens if there is no financial transaction related to the agreement?) (3) Are such agreements always anti-competitive? (4) Is the assessment of such agreements conducted under a per se approach or the rule of reason approach?

Finally – time permitting – mergers relevant to competition between originators and generic pharmaceuticals may be discussed (section III).

1. Recent developments and regulatory measures affecting generic competition

1.1 Favouring generic competition and price competition in the pharmaceutical sector through regulatory intervention

The Chair noted that governments often use a wide variety of mechanisms to increase the use of generic drugs. He first turned to Japan to explain the success and competition effects of their 2007 and 2013 action plans that aimed directly to increase the use of generics.

The delegate from **Japan** explained that the penetration ratio of generics used to be very low in Japan and this fact was related to the national health insurance scheme. In Japan, the government set the prices of prescription drugs and originator drugs were often much cheaper than in other countries. There was also only about a 30-40% price difference between the price of original drugs and their generic equivalent. In Japan basically everybody was covered by the insurance system under which patients had to pay only 30% of the price of prescription drugs. Because of all these factors, doctors were not eager to prescribe generic drugs and pharmacists were not eager either to sell the generic substitutes. Before the action plan, when the doctor had written the name of the branded drug on a prescription, the pharmacist was allowed to sell only that branded drug to the patient. So the first measure brought by the Ministry of Health, Labour and Welfare aimed to enable pharmacists to offer a generic equivalent – if it existed – even if the prescription mentioned the branded drug. At the same time, bonuses were provided to pharmacists to further incentivise the sales of generics. As a result the market share of generics rose from 16.8% in 2005 to almost 28% in 2013. However, the government remained under pressure to further reduce medical expenses, so additional measures were adopted to increase the share of generics – for example by education and communication promoting the equivalence and safety of generics.

To reflect the Chair's question about the welfare effects of these measures, the delegate from Japan stressed that they were certainly good from a cost point of view. The government had a deficit, so it tried to further reduce health expenses. Furthermore, along with the increase in the generics market share, new entries and mergers took place in the sector, so the authority has not seen much competition problems in the sector yet.

The Chair invited Bulgaria to introduce their instruments to promote generic products. Bulgaria was so successful in that area that some of the originator companies have actually left the market.

The delegate from **Bulgaria** noted that, although the Bulgarian pharmaceutical market was rather small, the penetration of generics was really high due to three regulatory measures. These measures concerned the Positive Medicines List (PML) containing all drugs (originals and generics as well) that are entirely or partially reimbursed by the national healthcare insurance fund (NHIF) in Bulgaria. First, regulation requires original drugs to be reimbursed by NHIF in at least three EU member states for minimum one year in order to be included in the PML; such a requirement is not applicable for generics. Second, the time period to start the effective reimbursement of a medicine by the NHIF is much longer for original medicines than for generics. The time of the whole process (that contains the market authorisation process, the inclusion on the PML and the process to start the effective reimbursement by the NHIF) takes 510 days for originator drugs, against 286 days for generics. Third, legislation empowers the NHIF to update the PML twice a month and to start the effective reimbursement of new drugs with the same frequency in case of generic drugs, whereas for original drugs both the update and the start of reimbursement happen only twice a year. These measures combined with other factors (e.g. low income population and the presence only of generic manufacturers in Bulgaria) have already made some originators leave the Bulgarian market.

The Chair asked whether there was an objective reason to have such a big time difference regarding the start of reimbursement of original drugs and generics, or it was purely discriminatory. He also wanted to know whether the Bulgarian Competition Authority was concerned about the fact that some players had left the market.

The delegate from Bulgaria replied that market exit was indeed a problem. Governments should be circumspect about the effects and final outcome of measures aimed to enhance generic competition.

1.2 Regulatory obstacles to competition in the pharmaceutical market

After the two examples on regulations to promote generic competition, the Chair invited Russia and France to share their experiences on how regulation could be just an obstacle to competition in the pharmaceutical market.

The delegate from **Russia** explained that the licencing procedure of medicines was indeed over-complicated in Russia. Market entry of new medicines consists of two stages in Russia. First, the examination procedure carried out by an executive authority, followed by the registration process carried out by the Ministry of Health (he noted that it led to quite an unclear situation to the Russian Competition Authority regarding the division of competences). The registration procedure also consists of two stages, i.e. an application for permission to carry out clinical studies and the actual registration of the medicine. Investigations and inspections carried out by the Russian Competition Authority during the last 2-3 years showed that the registration procedure (and the violation of these procedures) caused delays in the market entry of new medicines (taking an additional one, two or three years) and may have led to competition restrictions. In Russia, it is also not possible to refer to the results of clinical studies of original medicines when registering the generic version. Furthermore, clinical studies carried out abroad are also inadmissible. It is required to carry out local clinical studies whenever introducing any new medicine into the market. It seems problematic in the delegate's view, not only because it is very expensive, but also because it is impossible for generic firms to access the necessary data for carrying out clinical studies during the data protection period. This period is 6 years in Russia, which is in accordance with the WTO TRIPS agreement but longer than in other TRIPS member countries.

As to what the Russian Competition Authority did in such a disastrous situation, the delegate explained that they had been in consultations with the Ministry of Health and with international pharmaceutical companies for a long time. Although they sometimes had different views on the same provisions and agreements, he believes they will soon reach a successful outcome in this field.

The Chair noted that the level of generic penetration differs from one country to the other; in some countries (e.g. Germany, the US and the UK) generics penetration is quite high, whereas in others (such as France) it is rather low. The Chair asked France about the extensive study carried out by the French Competition Authority (FCA), which revealed obstacles to generic entry and offered suggestions for regulatory improvements.

The delegate from **France** noted that the FCA had launched a sector inquiry in the drug distribution sector with the exclusion of medicines sold in hospitals. They launched a long consultation process with all stakeholders who submitted vast written contributions. On that basis, the FCA released a report with some suggestions in December 2013. Similarly to other countries, French regulation also aims at promoting generic entry and competition. However, regulation sometimes still raises obstacles to the spread of generics. In France pharmacists have had the right for 15 years now to substitute original drugs with generics; financial incentives were even offered to pharmacists to encourage this substitution. Other measures have been adopted to incentivise doctors to prescribe medicines on International Nonproprietary Names (INN) instead of the brand name. There is a list of generics in France; pharmacists can substitute

original drugs with their generic equivalent provided it is on the generic list. However substitution can be prevented by doctors if they indicate "non-substitutable" on the prescription.

What happens in France is that doctors do not have thorough knowledge of medicines: they get most of their knowledge from pharmaceutical companies' visits to introduce their (branded) drugs. This has induced distrust on the part of doctors against generics and it has encouraged them to prescribe branded medicines instead of using their INN equivalent. Another obstacle revealed by the sector inquiry is that the list of generics is rather narrow in France, compared to other countries like Great Britain and Germany. Paracetamol or aspirin-based medicines, for example are not included in the generics list, even if these drugs are frequently used by consumers. There are many manufacturers of paracetamol or aspirin that can be bought without prescription, but because consumers are not aware of the generic versions, they tend to buy the branded version. One of the paracetamol brands is the fifth most reimbursed drug by the public health insurance system in France, so this subject is an important one in terms of the financing of the public health system. That is why the FCA suggested broadening the repertoire of the generics list to include e.g. paracetamol and aspirin. This suggestion is however still under discussion.

The Chair concluded that the regulatory environment could have quite opposite or diverging effects across the countries. Regulation can favour generics and enhance competition in some countries, whereas in others it may restrict competition. In this latter case, competition authorities tend to have limited tools to promote regulatory reforms because of strong resistance on the part of the health authorities. The Chair welcomed further remarks on this topic and gave the floor to Costa Rica.

The delegate from **Costa Rica** emphasised that the Costa Rican Competition Authority focused on advocacy in order to eliminate un-necessary regulations and enhance competition in the pharmaceutical market. She observed that there were lots of barriers to entry e.g. in the registration process in the medicine industry. Because of this regulatory environment and because Costa Rica's health insurance system covers almost everybody in Costa Rica, the government's healthcare expenses are huge.

The Chair noticed that competition authorities, which usually share how successful their advocacy efforts can be, do not seem to have succeeded in influencing other parts of government in this sector. He gave the floor to Norway for comments.

The delegate from **Norway** explained that Norway's regulatory framework had been quite successful in this regard. The penetration ratio of generics is fairly high in Norway mostly due to the so-called "ladder price model". It implies that, upon the introduction of generic competition, the state would immediately cut the price by 35% of the drug that is being refunded. This allowed price cuts of 90% after a year and a half from the generic entry Thanks to this model, the state has saved a lot of money, while the role of the Norwegian Competition Authority consisted in advocating extended use of the model. The delegate acknowledged though that pharmaceutical companies may want obviously to delay the development of a stable generic competition. The Norwegian Competition Authority has not had any case in this area yet, but they are in contact with relevant authorities on a regular basis.

The delegate from **Russia** completed his former statement by referring to some of the successes achieved to promote competition in the pharmaceutical markets in Russia. Changes were brought to the public procurement legislation in this sector over the last few years in order to enhance competition and reduce public healthcare expenses. For example, all public bodies must purchase medicines based on INN and launch separate tenders for each INN. Purchasing medicines by brand name became very limited and restricted to those drugs included in a specific list approved by the government. Upon suggestion from the Russian Competition Authority, the Ministry of Health issued an order a year ago prompting doctors and medical workers also use the INN name – or a grouping name if there is no INN name – when prescribing a medicine. Last, discussions are under way regarding the responsibility of doctors who prescribe

medicines in a wrong or illegal way. The delegate reiterated his belief that the improvement of the situation was only the matter of time in Russia.

The Chair thanked Russia for explaining that the situation was not as bleak as it seemed at first sight.

2. Anti-competitive strategies and antitrust enforcement

2.1 Unilateral practices by pharmaceutical companies

The Chair introduced the next topic, namely unilateral strategies adopted by pharmaceutical companies to stifle competition. He invited Professor Hemphill to give an overview of some of the latest unilateral practices that have been observed in the United States.

Prof. Hemphill introduced the price effects of generic entry with a diagram on the price changes of Prozac. The price of Prozac showed an upward trend until August 2001. At that time, a key patent on Prozac expired and another was successfully challenged. At first, the branded firm faced just one generic competitor on each strength, and prices started to fall. The decrease in price got even more dramatic in February 2002 upon entry from other generic companies.[1] Further US experience also showed that prices fall only by around 10% in case one generic company enters the market and more serious price drop would only start upon the entry by more generic competitors. This of course generates an incentive on the originators' part to restrict generic entry. The intensity of this problem depends also on whether there is room for market penetration and on the regulatory environment. He then introduced two types of unilateral practices/strategies that raise particular competition concerns: product hopping and the manipulation of the patent or the regulatory process.

Regarding product hopping, he explained that, from a certain point of view, product hopping could seem to be a good thing. Product hopping may involve a new dosage, a new formulation or a new variant of the same drug, fewer side effects, etc. Such product improvements can be made "in house" (i.e. by the same pharmaceutical firm) or through acquisition. The story becomes "interesting" if the newer drug enjoys a stronger and longer lasting patent protection, whereas the original drug is soon going off-patent. In this case there is an incentive for the originator company to move doctors and patients from the original drug to the new drug. There are different strategies to do so, including: (a) promoting the new drug differentially; (b) raising the relative price of the old drug; or (c) withdrawing the old drug from the market. The idea behind such strategies is to make life more difficult for generic competitors: by the time generic approval has been obtained, the market has already moved on to the new, protected drug. Prof. Hemphill raised some considerations/questions to take into account in a competition analysis: (1) Is the new product any better than the old one? (2) Are consumers left with a choice? (3) Was the original product withdrawn or is it continued to be on the market? (4) In case of withdrawal, was there a time gap? Was the old product withdrawn from the market before the new product received generic approval?

The assessment and outcome of product hopping cases differ from one another. In the US Tricor case, which involved multiple product switching, the judiciary was willing to see an antitrust claim. In other cases, where no product withdrawal was involved,[2] the judiciary didn't see any competition concern. Product hopping cases have proliferated during the last years: e.g. the Losec case in the EU, the Gaviscon case in the UK and the on-going investigation over Patanol in Canada. The defences raised in these cases – although being complex – are worth considering: (1) Isn't this a matter of product design? (2) If innovators

[1] Remark: the US legislation gives a 6 month exclusivity period for the generic firm that first litigates successfully a patent of an originator drug. (So at that time between July 2001 and February 2002 there was only one generic competitor for each strength of Prozac.)

[2] Like the case involving a product switch from Prilosec to Nexium in the US.

want to innovate and further improve their products, to what extent would competition enforcement want to interfere in this business process? (3) Is there a cognisable reduction in competition? Surely it is bad for generic firms, but does competition policy impose an obligation on innovators to make life easier for generics?

Turning to patent manipulation or the manipulation of the regulatory regime, Prof. Hemphill introduced two broad categories of conducts: (a) improper acquisition of a patent, and (b) assertion of a patent (in litigation) that the pharmaceutical company actually does not or should not have. This issue gets interesting when the abuse of the patent system intersects with an abuse of the regulatory system: for example, when an originator asserts a patent that later turns out to be meritless just in order to delay generic entry. Many jurisdictions struggle with such issues. Various questions are worth taking into account in the evaluation of these practices: (1) Should competition policy really be involved in cases concerning the manipulation of the regulatory structure? (He noted that examples so far suggest that it should. [3]) (2) Even if prices are higher for a longer period than they otherwise would be, does that affect the quantity of drugs on the market that would necessarily raise a competition concern?

Prof. Hemphill emphasised the importance of focusing on the effects that these practices have on the quantity of drugs. It seems generally accepted that quantities rise when prices fall. But in a highly regulated market like this, where the government is the principal purchaser, it might not be the case. He left the question open as to whether it really is so important to focus on the prices of drugs even where they might not have any quantitative effects.

The Chair thanked Prof. Hemphill for the excellent introduction to the topic. He then turned to the delegations to hear more on unilateral practices that have raised competition concerns.

2.1.1 Product switching/product hopping

Starting with product hopping, the Chair invited the UK to explain the Reckitt Benckiser product hopping investigation in the UK.

The delegate from the **United Kingdom** explained that the case involved Reckitt Benckiser's Gaviscon products (alginate based compounds used to treat acid reflux, gastro-oespohageal reflux disease and dyspepsia). Reckitt Benckiser's original drug was called Gaviscon Original. After the patent of Gaviscon Original had expired but before a generic name was introduced, Reckitt Benckiser launched a new product, called Gaviscon Advanced Liquid and withdrew Gaviscon Original from prescription sales (it was still available to purchase over-the-counter). To put the conduct into context, he explained that if a doctor prescribed a drug by a brand name in the UK, the pharmacist had to provide that branded drug, which could not be substituted with a generic alternative. In the UK, when a branded drug comes off-patent, the authorities introduce a generic name that doctors can apply to any generic equivalent of that drug. If the generic name is used on a prescription, the pharmacist is free to provide any appropriate drug. The OFT considered in its Decision that the withdrawal of the original product was with the intention of limiting pharmacy choice and hindering competition from suppliers of generic medicines. The delegate considered it a fairly straightforward case, in which Reckitt Benckiser admitted liability and paid a fine under the terms of the settlement with the OFT.

The Chair noted that product hopping cases were also found in the US and he invited the US delegate to provide further insights on the issue.

[3] Like the Astra Zeneca case in the EU or the US Supreme Court's opinion on the Actavis case.

The delegate from the **United States** could not report on any specific example. Yet she confirmed that product hopping was definitely an issue the FTC is interested in and monitoring. She noted that the challenge is always to draw the fine line between true innovation – which is definitely worth incentivising – and a strategy that is not beneficial for consumers.

2.1.2 Ever-greening

The Chair moved to another type of unilateral conduct: "ever-greening". He referred to the Italian Pfizer case in which Pfizer tried to delay generic entry by asking for a divisional patent for the same drug. He asked Italy to share the analysis conducted by the Italian Competition Authority in this case.

The delegate from **Italy** explained that Pfizer had held a European patent for the active substance of its anti-glaucoma eye drops. This patent was recognised in different EU member states just as in Italy. However, the patent in Italy would expire earlier than in other countries (in 2009), because Pfizer failed to ask for a supplementary protection certificate in Italy. In 2002 – 7 years before the expiration of its patent in Italy – Pfizer filed an application with the European Patent Office for a divisional patent regarding the same drug. The divisional patent was granted but it was validated only in Italy. Based on this divisional patent, Pfizer requested a supplementary protection certificate in Italy that it could otherwise not have obtained. The Italian Competition Authority (ICA) launched an investigation and concluded that no new product or new development had been released based on the divisional patent, so the only aim of the application for a divisional patent was to delay generic entry in the Italian market. On appeal, the court confirmed ICA's decision that Pfizer's conduct was abusive.

The Chair invited the experts to comment on the case.

Prof. Hemphill asked why – if he understood correctly the chain of the logic – the ICA thought that the issuance of a divisional patent would generate a seeming obligation to launch a revised product.

According to the Italian delegate, a proper use of the patent law required that, after obtaining the divisional patent, the firm should have launched a new product or at least should have developed/improved the original product. Since none of these happened, the application for a divisional patent was merely instrumental in order to prolong the patent protection of the original drug.

By analogy, Prof. Hemphill referred to the "Orange Book" in the US. US law obliges drug makers to list their patents in the Orange Book. However, originator companies supposed to list only those patents that cover a drug that is actually marketed. For example, if a company has a patent for an alternative crystalline structure of a drug, but which is not marketed, it should not be listed on the Orange Book. But if the company gets it listed after all, and sues a generic company based on that patent, it could delay entry. So it is not the same thing as in the Pfizer case, but it is slightly similar in the sense that it gives a tactical advantage that limits generic entry as a consequence.

Mr. Subiotto stressed out that it is dangerous for antitrust law to intervene in the use of the regulatory process by companies. If regulation existed and it permitted Pfizer to obtain a divisional patent, then this patent meant to exclude competition. It would make more sense in this case to review regulations in order not to allow pharmaceutical companies to obtain patents in such circumstances.

The Chair gave the floor to BIAC.

The delegate of **BIAC** drew attention to the life cycle management of pharmaceuticals, which is different from that of normal consumer products. In case of an iPhone, for example, consumers' choice might be influenced by the fancy packaging. But in case of medicines, it is usually not the consumer who makes the decision and it is highly unlikely that the company would get higher prices based on just the

packaging for instance. There are certainly fine lines and grey zones concerning possible mischief or abuse, but one general conclusion can be drawn though: as soon as the patent on an active substance expires (especially in the case of block buster medicines), there is generic entry on the market. BIAC strengthened the importance of being cautious in dealing with the inherent conflicts between competition law and IP rights (patents).

2.1.3 Refusal to give access to essential patents

The Chair introduced to the next controversial type of unilateral conduct, namely the refusal to give access to essential patents. This type of conduct raises various questions, such as: (1) What is an essential patent? (2) Under which conditions would refusal to grant access amount to an abuse? The Chair invited South Africa to share its experience in the case involving GlaxoSmithKline (GSK) and Boehringer Ingelheim (BI) refusing to give access to essential patents.

The delegate from **South Africa** emphasised that South Africa was a major centre of HIV/AIDS epidemic, which is a huge public healthcare issue. In 2002 and 2003, the South African Competition Commission received complaints concerning the practices of branded pharmaceutical companies (GSK and BI) in respect of HIV-related drugs. The complaints were two-fold: they raised claims of excessive pricing of the patented drugs and of refusal to give competitors access to essential "facilities" in South Africa. In other words, these major branded pharmaceutical firms failed to licence their patents on reasonable terms to generic firms in a country where the targeted disease was a huge public healthcare issue. The firms were willing to settle the case during the investigation, so there was no competition enforcement decision in the end. Under the settlement, both companies agreed (a) to grant licenses to the generic firms, (b) to permit the licensed firms to sell generic products in the region, (c) to permit the licensed generic firms to mix the drugs so as to create better combinations for patients (d) not to require royalties above 5% of their net sales. This settlement enabled generic competition and led to lower prices to the benefit of patients. (A 2006 study showed that the price of one of the branded drugs to cure HIV fell by more than 50% from 2002-2003 to 2006, while the generic equivalent was even cheaper.)

The Chair asked whether any generic company had the right to ask for a licence or whether there were some minimal conditions to meet.

The delegate from **South Africa** responded that the competition implications could not be tested since the companies were willing to settle the case. He also pointed to another case conducted against the same two firms and involving different but also HIV-related products. The companies were again willing to settle the case, so generic firms penetrated the market quickly here, too.

The Chair gave the floor to BIAC for their views on essential patents and the compulsory sharing of such rights.

The delegate from **BIAC** noted first that BIAC was not against curing AIDS in South Africa. From the business perspective though, it is very important, in BIAC's view, to optimise outcomes for consumers, and this means more than just reducing costs. It also means promoting innovation for newer and better pharmaceuticals, the returns of which are very speculative as timelines are long and costs of gaining approval are very high. He was pleased to hear Russia's contribution on the advocacy role of competition agencies. Such advocacy efforts may help streamline processes for approval of branded drugs. Generics provide a huge benefit to consumers by reducing prices often significantly, but their existence is a consequence of innovation by originator companies and of the existence of originator drugs. So the most important goal should be to strike the right balance between maintaining high incentives for innovation while promoting the benefits that come hand in hand with generic competition.

BIAC's delegate also emphasised the importance of taking into consideration the fact that very few drugs actually make it through the final approval stage to be marketed. The drugs that get into the market are the ones considered by originator companies to have strong commercial potential. (There are exceptions of course: a pharmaceutical company may find the medical need great enough to justify further development of the drug, even if its commercial potential is weaker.) BIAC emphasised the need for a predictable system for the return on investments for the drugs that finally got into the market. In contrast, competition enforcement measures that force access to legitimately patented products create uncertainty and disincentives to innovate. BIAC concluded by confirming its respect for the purpose behind the South African Competition Agency's efforts. In that instance, it seemed that the end justified the means, but he doubted that in other jurisdictions, similar use of competition policy tools would be appropriate.

2.1.4 Misleading information tactics

The next type of unilateral conduct for discussion was misleading information tactics. Starting with the misinformation of regulatory bodies, the Chair asked Chinese Taipei to share their experience with a civil case that involved misleading of the IP courts.

The delegate from **Chinese Taipei** explained that Chinese Taipei is a small open economy with only generic manufacturers. Most competition issues dealt with so far, emerged between foreign originator and domestic generic firms and concerned IP rights. In the quoted civil case, Takeda Pharmaceuticals, a Japanese originator firm, and Genovate Biotechnology, a Chinese Taipei generic firm, manufactured drugs for diabetes using the same active ingredient. In 2004, Takeda filed a provisional injunction application, claiming that Genovate had infringed its patent. The court granted the application, so the generic drug could not enter the market. Genovate filed a civil lawsuit with the intellectual property court for unfair competition. Takeda won the case in first instance. On appeal, the court of second instance declared that Takeda did not own the patent it claimed, since it intentionally provided false information to get a preliminary injunction against generic entry. The court of second instance found that Takeda violated the Fair Trade Act and imposed the payment of compensatory damages. The Supreme Court confirmed the latter judgment. This case is one of the few examples in which the parties did not turn to the Fair Trade Commission, but filed a lawsuit in court instead. The court did not consult the Commission, but this may highlight the importance of enhanced co-operation between the judiciary and the Commission in the future.

The next type of misinformation tactics consist in the misinformation of doctors. The Chair invited Finland to illustrate this type of practice through its recent enforcement practice.

The delegate from **Finland** reported on an exclusionary case, in which the originator company suggested, through its marketing materials, that doctors deny generic substitution of Clozapine, its original drug to treat schizophrenia. The company claimed that the generic drug was not that efficient and that it could cause more serious side-effects than its originator drug, referring to scientific articles to support this view. The Finnish Competition Authority acknowledged that such a conduct could detrimentally affect the reliability of generic drugs and thus the pharmaceutical substitution system. But the authority also found that doctors were aware of the potential risks and side effects of such medicines, so it remained unclear whether the originator's conduct had any actual impact on the doctors' decisions. The authority therefore closed the case for lack of adequate evidence.

2.1.5 Exclusionary loyalty schemes

The Chair switched to the topic of exclusionary loyalty schemes and invited France to introduce its Schering-Plough case, which involved loyalty discounts used for anti-competitive purposes.

The delegate from **France** explained that Schering-Plough laboratory's patent for Subutex drug had expired and that, three month before market entry by its generic competitor, Schering Plough had started offering large discounts (similar to loyalty discounts) to pharmacists on the sale of Subutex. The only purpose of the discounts was to prevent pharmacies from obtaining supply from the generic manufacturer. According to a regulation in France, generic firms are allowed to offer much larger discounts (10.74%) than originator firms (2.5%). To bypass this regulation, Schering-Plough paid pharmacists for alleged services. The FCA determined, however, that the volume of granted discounts did not depend on the service pharmacists provided, but on the quantity of the purchased drugs. As a consequence, pharmacists obtained stocks of Subutex that were so massive there was no room left for the generic version when it entered the market. The FCA decided in December 2013 that Schering-Plough abused its dominant position through its discount strategy, and imposed a fine of €15.3 million on the company.

The Chair found the case quite extraordinary, since it considered the conduct of a dominant firm to lower its prices abusive. He asked the experts whether they heard of any similar case.

Prof. Hemphill observed that the Schering-Plough case was a bit different from classical loyalty discount cases as it involved a regulatory rule that had been violated. The company claimed to do one thing (paying for special services offered by pharmacists), whereas in fact it was doing something else (giving quantity-based loyalty discount). In other loyalty discount cases (such as the recent Intel decision) there was no such regulatory environment, so the question is again, whether the violation of a regulatory rule raises a competition concern in the classical sense of competition law infringements.

The Chair remarked that he was a bit confused about this French case. As he summarised it, there was an originator firm whose patent had expired and the generic was just about to enter the market. In the meantime, the originator firm reduced its prices, leading pharmacists to stock from the branded drug, while at the same time they knew the generic drug would enter the market soon. So he wondered what the obligation born by a dominant originator company was: to facilitate market entry of the generic drug?

The delegate from **France** replied that the discount was actually not reflected in the final price of Subutex, because its price was regulated. But the conduct of Schering-Plough led in fact to favouring the sales of Subutex over the generic version. And since generic drugs are usually 20% to 40% cheaper than originator drugs, these discounts actually prevented the health insurance system from achieving savings from the sales of the cheaper version.

The Chair said he could understand the goal of the decision. But according to him the real question here is whether the company's behaviour was the consequence of a bad regulatory environment rather than a question of abuse of dominance in the classical sense of competition law.

The delegate from **France** stated that there was a regulation in France that limited the amount of rebates an originator firm could grant, and that this regulation was violated by Schering-Plough with the only purpose of preventing generic entry.

The Chair concluded that many examples were provided revealing questionable strategies developed by originator companies. These cases showed that originator firms have quite some imagination when it comes to maximizing their profits. He wondered though how competition authorities detected these cases. Were they found out upon the authority's own initiative or upon complaints against such presumably anti-competitive practices? He noted furthermore that many of these practices seemed ambiguous from the strict competition point of view, since sometimes it seemed sufficient to prove that the originator company benefited from the "misuse" of regulation (e.g. it violated a certain regulatory rule that was not strictly linked to competition rules) in order to establish that the company abused its dominant position.

2.2 Anti-competitive agreements to affect the competition between originator and generic drugs

2.2.1 Pay-for-delay agreements or reverse payment agreement

Anti-competitive agreements constituted the second main part of the discussion on competition enforcement, with a focus on so-called pay-for-delay settlements. The Chair introduced the topic by underlining that it had been a key topic on both sides of the Atlantic recently; it was therefore important to understand the main features of such agreements: e.g. what is the theory of harm or how to distinguish between agreements that violate competition law and agreements that may be lawful? The Chair turned first to Prof. Hemphill for a general overview and analysis of the issue.

Prof. Hemphill summarised first the theory supporting why competition authorities usually find a competition concern arising from reverse payment agreements. These agreements are settlements of a patent litigation between a branded and a generic drug manufacturer, where the generic firm is trying to come into the market prior to the expiration of the originator's patent. Such patent litigation is often settled in a way that involves (a) a large payment from the branded firm to the alleged infringing generic firm and (b) a requirement that the generic firm abstain from competing for a certain period of time. During the litigation, the generic firm would try to push for as early an entry date as possible (so it wants basically the same thing that consumers want), whereas the branded firm is concerned about delaying the generic entry date as much as possible. Prof. Hemphill noted that a mere compromise on entry dates would not raise any competition concern in itself. The problem occurs where the interest of the generic firm is influenced in a way that is beneficial to the generic firm but not to consumers. He introduced a slide showing different outcomes of litigation in terms of the entry date of the generic drug. If the generic firm wins the litigation, competition (hence lower prices for consumers) starts immediately upon the end of the litigation. If the originator firm wins the litigation, there is no competition though until the expiry of the originator's patent. And that is a perfectly legitimate situation as well. The third outcome is when the originator and the generic firm decide not to litigate to death, and reach a settlement instead. Such settlement can be expected to reflect the relative bargaining power of the parties. In case of a strong patent (i.e. on the active ingredient), the originator would probably win the litigation, so the entry date would be later, closer to the expiry date of the patent. Competition concern arises if a large payment from the branded firm to the generic firm moves the generic entry date later than it would otherwise be. It means that higher drug prices will continue for a longer period and that is a sign that something troubling is going on.

In the US though, parties still have the opportunity to explain that such a settlement is pro-competitive. Prof. Hemphill showed the internal evaluation by an originator firm on the future profits for the originator and the generic firms depending on the various possible outcomes of the patent litigation. Then he showed how much the originator would need to pay the generic firm for the latter to agree on a later entry date.[4] The parties can work out the different ways in which such payment would be conveyed, through various side deals.

Prof. Hemphill reminded that the US Supreme Court's opinion in the Actavis case established a rule of reason evaluation of such agreements, which had generated a lot of litigation since then. He showed the list of the 19 different drugs that were currently the object of either FTC cases or private cases concerning reverse payment issues.

[4] These documents were revealed in the currently pending FTC case concerning Androgel (a testosterone replacement drug).

Prof. Hemphill clarified that a large payment could be a problem in case of a strong patent as well as in case of a weak patent.[5] He observed in fact that not all patents were created equal. These days originator firms are obtaining more and more patents than in the past. The number of listed patents per drug roughly doubled from 1985-1987 to 2000-2002. Most of these patents are not active ingredient patents, but secondary patents. The 'nature' of a patent plays an important role in the outcome of the litigation. In case of active ingredient patents, the originator company would almost always win, whereas in secondary patent litigation, originator firms won only less than one third of the cases. In the US, nearly all cases of reverse payment settlements related to secondary patents.

Prof. Hemphill highlighted two additional complications that occurred in the US regarding pay-for-delay agreements: First, it is not always obvious what counts as a payment. Besides payment in cash, lots of other variants have already occurred to compensate the generic firm for the later entry date. For example in case of authorised generics (that is a generic version of the original drug launched by the originator firm itself), if the originator firm promises the generic firm to abstain from launching its authorised generic. Such commitment is equivalent to a value transfer. It might even be worse than a traditional money transfer since it is sustaining an anti-competitive market structure for a longer period of time. Second, side deals may complicate the assessment: e.g. when the generic company agrees to stand ready to manufacture or to promote the branded original product. The burden of proof is not obvious in cases involving side deals. However, seeing such kind of side deals that would be unusual except in the context of a settlement, should be suspicious.

Mr. Subiotto confirmed that the determination of what amounts to a 'payment' was a core question in Europe, too. A common form of settlement between originators and generic firms consists in the originator granting the generic firm an early entry license for certain countries in the EU, but not for others. He wondered whether this could count as a value transfer to the generic firm in exchange for its staying out of the market in selected countries until the date of the patent expiry.

Mr. Subiotto then turned to introduce the role of the regulatory framework in the evaluation of pay-for-delay agreements. The regulatory environment in Europe is different from the US, and its role on companies' behaviour is even more important here. Referring to the recent Lundbeck case, he noted that the European Commission (EC) had set two criteria for assessing the legality of reverse payment agreements: (1) whether there was a restriction on generic entry and (2) whether there was a cash payment. If these two conditions are met, the agreement is deemed illegal by object according to the EC. This contrasts with the US the Supreme Court's Actavis ruling, which subjected the assessment of reverse payment settlements to a rule of reason.

Mr. Subiotto suggested that the assessment should take into consideration the functioning of the patent enforcement system, since reverse payment agreements might in fact be explained by the need to counter-balance the imperfections of the patent enforcement system. The main imperfections are three-fold as per Mr. Subiotto's slides: (1) In the EU, there is limited availability of effective preliminary injunction (ex ante enforcement). It means that if a generic comes up with a product that is potentially infringing the originator's patent, it is difficult for originator to keep that generic off the market. That is due to basically two factors. First, obtaining a preliminary injunction takes a long time. The experience of Lundbeck showed that the fastest procedure took place in Denmark, which still took several months. Second, in some countries, like in Germany, preliminary injunction is not obtainable if the patent concerned is being questioned. So by the mere fact of having started litigation in Munich for example, German authorities would not grant a preliminary injunction. (2) The originator company would never be fully compensated for the losses caused by the entry of an infringing product due to a number of factors: (a) In some EU

[5] By weak patent he meant a patent that, if litigated, the conclusion by a court would likely result in generic success; either an invalidation of the patent or a non-infringement decision.

countries, the price of pharmaceuticals is set by regulation. Statistics show that this regulated price decreases upon infringing generic entry and will never increase back to its original point, even if the originator wins the case. Furthermore, some countries have a reference price system (taking into account the price level in other countries). If these countries take into account the price of the country where entry by an infringing generic took place, the price decrease in the latter country has a spill-over effect on countries applying a reference price system and might lead to an unstoppable waterfall in the EU. (b) Other national legislations command that the originator be paid a reasonable royalty rate rather than being compensated fully for the damages suffered. (c) Litigation costs are hardly ever compensated fully either. (d) Finally, Mr. Subiotto referred to the so-called and often experienced "judgement proof" problem. It occurs where a generic firm loses litigation and liquidates to only come up under another firm name. He showed a graph quantifying the potential loss incurred by the originator and the generic firm under different litigation outcomes in an effective patent system and in a flawed patent system. The numbers confirm that the patent enforcement system does play a very important role in the incentives for generic companies to launch a potentially infringing product or not. This pattern qualifies as an "invisible value transfer" from the originator to the generic company.[6] (3) Finally, in the absence of a unified patent judiciary, the originator has to start proceedings in each EU member state if it wants its patent to be enforced across the EU.

To conclude, Mr. Subiotto emphasised that the existence or the size of the payment could not be the main legal standard to assess patent settlements. As a consequence of such an approach, litigation is flourishing, while the number of settlement agreements has drastically dropped in the EU. In his view, as long as the restriction of generic entry and the settlement are within the scope of a valid patent, the settlement achieves the same result as the one the patent holder would have reached by enforcing its patent in court. He believes that this should be the relevant test in the EU. He noted that Justice Roberts advocated the use of the same legal test in the Supreme Court judgment in Actavis, but it was rejected.

The Chair gave the floor to BIAC.

The delegate from **BIAC** shared Mr. Subiotto's finding that the European regulation and environment was dramatically different from the US in many respects. The most important and most problematic difference, according to BIAC, is the ignorance of the irreparable harm that might be caused to the originator company even if it won the patent litigation. In the US, the winner gets an adequate compensation for the loss it suffered. In Europe however, the IP litigation and enforcement system is highly fragmented, inefficient and often requires patent litigations in multiple jurisdictions. It is complex, costly and the outcome is ambiguous. He also referred to the pitfalls of a reference price system in case of an infringing generic entry. Referring to the Lundbeck case, BIAC indicated that Lundbeck had analysed more than 600 samples from generic competitors and had found an infringement of its process patent in each case. Based on these findings, the company opened litigations in more than 20 jurisdictions and has not lost a single case. But because of the reference price system the company still suffered immediate losses.

BIAC further observed that, at the time of the sector inquiry, the European Commission seemed to favour a rule of reason assessment, but since then it seems to have moved to a per se ban on reverse payment agreements.

6 This invisible value transfer means that the generic company does not fully internalise the harm (caused to the originator) resulting from its infringing entry, which may therefore induce a distorted incentive to enter the market even if it knows its product infringes a valid patent.

BIAC last insisted on the need to reform the European litigation system. Europe really needs a unified patent litigation court. It was mentioned in the European Commission's sector inquiry as well. An early dispute resolution, close to a notification system, would also be beneficial.

The Chair summarised that, given the presence of some alternative costs (e.g. patent litigation in courts entails high cost in itself), not all settlements were a sign of anti-competitive behaviour. The Chair asked the experts to comment on how to compute these alternative costs in order to take them into account in the evaluation and to be able to determine whether a payment had anti-competitive elements or not.

According to **Prof. Hemphill**, the alternative cost is a value transfer from the originator to the generic firm, which is larger than the litigation cost that would have been avoided. He noted that the cost of litigation used to be rather high in itself; it might even be tens of millions of euros. But the revenue generated from originator drugs could reach billions of euros. So he thinks that the aim of the value transfer is basically to save litigation costs. The defendants should then be allowed to explain why the settlement actually led to more competition. He thinks that this would be the correct structure of the test.

Mr. Subiotto suggested to take into account whether a settlement is within the scope of the patent or not. If it is, then the patent holder does nothing more than what it could achieve in court by enforcing its patent. The second criterion is that there must be genuine patent dispute. If those two conditions are met, the size of the payment should not be a criterion to determining whether an agreement is anti-competitive or not. As mentioned before, litigation costs are just one of the elements that the originator has to bear in the EU. He also referred to the irreparable damage mentioned by BIAC. Irreparability by definition means that the amount paid by the patent holder is immeasurable, so this amount should not be taken into account. He believes that if the payment is lower than the expected loss – based, for example, on the company's internal estimates – and the two criteria mentioned above are met, a settlement involving a payment shouldn't raise any concern.

Prof. Hemphill expressed some concerns with two elements of the reasoning of Mr. Subiotto and BIAC. First, according to their logic, the originator would be entitled to settle for what it would get by winning the litigation. So the originator would be permitted to pay for delaying the generic entry until the protection of its patent expires. This approach does not take into consideration the 'nature' of the patent (i.e. whether it's a weak patent or not) or the actual time of the delay as long, as it does not exceed the date of the patent expiry. He highlighted though that there is a difference between having won the case and trying to win it.

His second observation concerned the relevance of imperfections of the patent system. In this respect, under Mr. Subiotto's proposal, the originator would be entitled to get even more than what it would get if it won the litigation or what the patent system permits, since it could sometimes not sufficiently compensate for the harm. He believes – in contrast – that competition enforcement should take the patent system as given. He referred to a Supreme Court decision from the 1930s called Fashion Originators' Guild of America v. Federal Trade Commission. In the US, original articles of fashion are not entitled to get copyright. So New York dress designers engaged in a boycott, through joint private action, to enforce the copyright they were denied. The Supreme Court stated that this conduct had been per se illegal and that the IP system had to be taken as it is.

Mr. Subiotto agreed that the patent system has to be taken as given. Thus competition authorities with non-technical people should not question whether a patent is a weak patent or a strong patent. He mentioned a case in which an internal document proved a business person's uncertainty about the outcome of a litigation. This document was taken as a proof that this settlement case concerned a weak patent and therefore was illegal. If antitrust law goes into this question about weak and strong patents, companies would no longer be able to settle with a payment and they would be obliged to go to court to litigate. The

problem is there are judges with varying quality and even a judgement in a country would not give full proof answer to whether a patent is valid or not. There are countries that are very strict with patents and declare patents invalid more frequently than other countries. He strongly believes that the establishment of a specialised, unitary patent court in the EU with qualified judges understanding patent law properly would solve this problem. This, along with a cheap and fast litigation system would be beneficial for pharmaceutical firms. He thinks that the present system in which antitrust law tries to compensate for these regulatory imperfections is not satisfactory.

To follow up on the experts' interventions, the Chair gave the floor to the US and the EU to hear their experience and views regarding pay-for-delay settlements and in particular whether a rule of reason or a per se approach should be followed.

The delegate from the **United States** thanked the experts for their overview of the topic. The FTC has been dealing with pay for delay agreements for more than a decade. Behind their enforcement activity, there has been a great deal of research into the competitive dynamics concerning the interaction between originators and generic companies. The theory of harm for pay-for-delay agreements is that the originator firm is using its monopoly profit and trying to avoid the risk of competition or the invalidation of its patent by paying generic competitors. The focus of the FTC is on whether the payment is in fact capable of distorting the bargaining process between the originator and the generic firm. When the FTC first started investigating this type of agreements and was successful in challenging them in the early 2000s, this effort dramatically reduced the number of such agreements. Later on, courts started however to apply a different approach, essentially based on "the scope of the patent" test suggested by Mr. Subiotto previously. As a result, the FTC lost many cases in courts and the number of pay-for-delay agreements increased. More recently – fortunately for the FTC – one of the appellate courts rejected the scope of the patent test and referred the issue to the Supreme Court to settle the diverging rulings by the appellate courts on this matter. This was the Actavis case, in which the Supreme Court reversed the scope of the patent test and established that patent settlements were not immune from antitrust scrutiny. The Supreme Court adopted a rule of reason standard and basically left it to the lower courts to determine whether a payment in the context of a patent settlement agreement was anti-competitive or not. The Supreme Court also expressed that a patent litigation was not even necessary in order to resolve the antitrust question.

In the US delegate's view, a payment raises concerns if it can distort the incentives of the generic company, i.e. where the generic company's incentive is no longer to achieve the best deal in settling a patent litigation, but to share the originator's monopoly profit. The US delegate indicated that the key question in assessing pay-for-delay agreements is whether the originator firm's payment induces the generic firm to stay out of the market, based on two factors: (1) is there a large payment from the originator firm to the generic firm, and (2) has the generic company agreed not to compete for a certain period in exchange for that payment? The agreement starts to get problematic if the value transfer exceeds the amount that would have been saved on litigation, since it induces the generic firm to enter into an agreement that is ultimately detrimental for consumers. If the enforcement authority can prove both criteria, the originator could still offer evidence that the agreement is not anti-competitive. She noted that the FTC has two pending cases in this field: the previously-mentioned Actvis case and the Cephalon case.

Regarding the types of payments, the US delegate observed that, in the early cases, the transactions usually manifested in the form of cash payment. Since then, originator companies have become more sophisticated regarding the type of compensation, which may consist in: e.g. co-promotion deals; the originator company granting IP right licenses to the generic company; or the originator agreeing not to launch an authorised generic drug.

The latter example of authorised generics is another area to which the FTC is paying attention. The FTC issued two reports – an interim report in 2009 and a final report in 2011 – on what happens when the

originator firm launches an authorised generic. The reports showed that prices drop by approximately 10% when one generic drug enters the market and prices start to decrease even more dramatically when multiple generics enter the market. This means that the originator's agreement on not to compete with an authorised generic can be very valuable to the generic competitor, especially during the 180 days exclusivity period granted to the first generic filer in the US.[7]

There is also a great deal of private litigation in the US. The FTC has made an effort to also influence the development of the doctrine in this area by filing amicus briefs in cases concerning authorised generics and product hopping among others.

The Chair remarked that in some countries, like France, lawyers' imagination seems boundless to invent new services that could be rendered as payment. Sometimes these services or side deals included in the pay-for-delay agreements are not closely linked to the original object of the litigation. He then gave the floor to the EU.

The delegate from the **European Union** explained that, according to the European Commission (EC), there are different types of agreements and every single agreement should be assessed according to its own characteristics. These differences may relate to the type of the value transfer foreseen by the agreement (e.g. regular money payment or other type of value transfers), and to the context of the patent litigation (pay-for delay could happen with or without any patent litigation).

The EC takes three factors into account in assessing pay-for-delay agreements: (1) The agreement should take place between two parties that can be deemed potential competitors. (2) There should be a commitment by the generic firm not to enter the market or not to keep challenging the patent validity or the patent infringement claimed by the originator. (3) Last, there should be a value transfer that has the characteristic of being an inducement for the generic company to refrain from putting a competitive pressure on the originator. If an agreement contains all three features, the EC considers that this agreement has the potential of delaying or even preventing generic entry and therefore has the potential to infringe article 101 of the Treaty on the Functioning of the European Union (TFEU). An agreement that restricts generic competition deprives consumers from lower prices and an increase in each consumer's welfare; that could be a theory of harm. This does not mean however that all such agreements are illegal; it means that these agreements bear such risk and thus deserve competition scrutiny. The European pharmaceutical sector inquiry of 2009 concluded that generic entry leads to dramatic price reductions in the relevant markets. So an agreement that restricts generic competition deprives consumers from lower prices and this could be the theory of harm for pay-for-delay agreements.

The EU delegate further noted the criticism raised against the EC's allegedly unreasonable scrutiny of the pharmaceutical sector, which could prevent or deter pharmaceutical companies from settling their patent disputes. So the EC decided to launch a patent settlement monitoring system to observe the evolution of patent settlements in Europe. This monitoring showed that competition enforcement had not prevented companies from reaching optimal patent settlement agreements. On the contrary, the number of patent settlement has increased. In addition, the vast majority of settlement agreements did not raise any anti-competitive concern. Only a small range of patent settlements deserved antitrust scrutiny.

He reported that the EC adopted two decisions in the last few years on pay-for-delay agreements. In the Fentanyl case, there was no litigation at all, but still there was a pay-for-delay agreement. The type of the value transfer in this case involved a co-promotion agreement between Janssen-Cilag (an originator

[7] In the US the first generic company that files an application to launch a generic product enjoys a 180 days exclusivity period. During this period no other generic firm can enter the market, though the originator company can launch its authorised generic drug.

company owned by Johnson & Johnson) and Sandoz (a generic firm owned by Novartis). The agreement also contained a monthly payment from Janssen-Cilag to Sandoz. The size of the payment exceeded the profit that Sandoz could have obtained by selling its generic product. The EC found that this agreement delayed generic entry and kept prices high in the relevant market for 17 months, so it violated article 101 of TFEU. The parties did not appeal the decision. The Lundbeck case on the other hand involved patent litigations. In settling the litigation, the generic producers agreed not to enter the market in return for substantial payments from Lundbeck. (This payment included various forms of value transfers, e.g. distribution agreements and the purchasing of generic stock with the only purpose of destroying it.) In this case as well (just as in the Fentanyl case) the EC took into consideration the generic firms' expected profits in case of entry. The EC found that these agreements also violated article 101 of TFEU.

The EU delegate concluded that, in the EC's view, it is not acceptable for companies to pay competitors to stay out of the market at the expense of the European citizens. The EC will therefore continue to fight against these types of activities.

The Chair expressed his confusion given the press release of the Lundbeck case, which suggests that an agreement containing a value transfer was a "by object" violation of competition law, whereas the presentation from the EU seemed to suggest an effect-based analysis. He asked the EU to clarify its position.

The delegate from the **EU** explained that the EC considered these types of infringements a by object violations. It does not mean that any agreement that includes a value transfer is a per se violation of article 101 TFEU but that, taking into account the characteristics of the case and the specificities of the agreement at stake, it can be concluded that the object of that agreement was to restrict competition even though its effects may not be assessed.

The Chair asked the US to whether they saw any difference between the EC's and the FTC's respective methodology.

The delegate from the **US** replied that, based on what she just heard, both approaches seemed similar to her.

The Chair turned to the EU to explain to what extent the EC's approach differed from the FTC's.

The delegate from the **EU** explained that there were differences notably in the assessment of the inducement and of the commitment. There might be also differences in the approach, in the procedure of the enforcement, in the jurisdiction and in the institutional settings.

The Chair noted that there were a couple of other issues on the agenda, but since the most important topics were addressed, he proposed to close the Roundtable here and thanked the delegates, the expert and the Secretariat for their contribution and participation in this lively discussion.