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THE FUTURE OF PHARMACEUTICALS: ANTITRUST, IP AND REGULATORY CHALLENGES
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On 21st November 2024, the Department of Law at Roma Tre University hosted the conference titled 'The Future of Pharmaceuticals: Antitrust, IP, and Regulatory Challenges'. The event was organised by Margherita Colangelo, Associate Professor of Comparative Law at Roma Tre University, who introduced the conference. The conference is part of a long-standing tradition at Roma Tre University, where annual conferences have been held since 2015, focusing on the most discussed issues in competition law enforcement. This year's conference was devoted to the pharmaceutical sector, a field of particular relevance in the context of the application of competition law. Colangelo outlined the conference's aim to adopt a multidisciplinary approach to addressing some of the most recent issues in the pharmaceutical sector, taking into account the sector's unique intersection of intellectual property law, regulation, and competition law. She highlighted the inherent tension between concurring objectives in this sector, particularly the objective to promote innovation alongside the need to maintain contestable and affordable markets. In accordance with the intended multidisciplinary approach, the conference brought together a group of speakers from various backgrounds and with various expertise, ranging from legal scholars and economists to representatives of regulatory agencies and of the pharmaceutical industry. The first session, chaired by Andrea Guaccero, Professor of Commercial Law at Roma Tre University, focused on antitrust issues in the pharmaceutical sector. The second session, chaired by Elena Granaglia, Professor of Public Economics at Roma Tre University, was devoted to issues relating to intellectual property law and regulation.

The first speaker was Rieke Kaup from the European Commission, DG

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Competition. In her presentation, she provided an overview of recent EU antitrust enforcement in the pharmaceutical sector, highlighting key developments, such as the recent disparagement decision in *Vifor*[1]. She began by emphasising the societal importance of the pharmaceutical sector, noting how the recent pandemic underscored the importance of having well-functioning pharmaceutical markets. Kaup also stressed the challenge of balancing innovation with affordability. While the high costs of drug development often prevent the guarantee of affordable, cheaper products, these costs must be recouped through a limited number of successful drugs. She pointed out that if prices are set too low, innovation suffers; however, if prices are too high, national health systems may be unable to afford new medicines, rendering these innovations useless as inaccessible to patients. Given these challenges, Kaup highlighted the active antitrust enforcement under both Articles 101 and 102 of the TFEU in the pharmaceutical sector. However, she noted that enforcement under Article 102 TFEU has been more prevalent in recent years. Turning to enforcement under Article 101 TFEU, Kaup focused on cases involving pay-for-delay agreements. These are arrangements where an originator pharmaceutical company pays a generic producer to delay market entry, thereby maintaining high drug prices and harming health systems, which end up bearing the costs. Kaup pointed out that while such cases dominated recent years, they may be nearing their end, with the latest EU courts decisions in the *Servier*[2] and *Cephalon*[3] cases rendered earlier this year and one year ago, respectively. Kaup also briefly mentioned traditional cartel cases before moving on to discuss the current focus on unilateral conduct under Article 102 TFEU. She explained that the European Commission's enforcement with respect to unilateral conduct targets both 'classic' anti-competitive behaviours (eg, rebate abuse and predatory practices) and, most notably, more atypical abuses, for which normally the key test is merely whether the behaviour constitutes competition on the merits. Among the atypical abuses Kaup

[1] *Vifor (IV iron products)* (Case AT.40577) Commission Decision [2024].

[2] Case C-176/19 P *European Commission v Servier SAS and Others* [2024] OJ C/2024/4825; Case C-201/19 P *Servier SAS and Others v European Commission* [2024] OJ C/2024/4828.

[3] Case T-74/21 *Teva Pharmaceutical Industries Ltd and Cephalon Inc v European Commission* [2023] OJ C/2023/1139.

highlighted were disparagement, as seen in the *Vifor* and *Teva Copaxone*[4] cases, boycotts, vexatious litigation by originator companies, the misuse of divisional patents (also seen in the *Teva Copaxone* case), abusive acquisitions of intellectual property rights, and the exploitation of regulatory or patent systems, citing the *AstraZeneca* case as a prominent example. She noted that these latter cases are becoming increasingly common. Kaup then delved into some of the atypical abuses. First, she focused on a particularly atypical case, which is at issue in the ongoing *Zoetis*[5] case, where the alleged anti-competitive behaviour involved the termination of a pipeline project and the refusal to transfer the project to a third party. Specifically, the company may have used its power over the development of an alternative product project to terminate it and refuse its transfer to a third party which had exclusive commercialisation rights. She further addressed two other abuses: the misuse of the patent system and exclusionary disparagement. In the *Teva Copaxone* case, Teva was found to have abused its dominant position by exploiting loopholes in the European divisional patent procedures to extend the protection of its blockbuster drug, Copaxone. This allowed the company to withdraw patents and make it harder for competitors to challenge its patents. The second abuse involved disparagement. Teva spread misleading information about the safety, efficacy, and therapeutic equivalence of a competing generic version of Copaxone, information which, although not scientifically disproven, led to misleading conclusions about the generic product. The final part of Kaup's speech focused on the recent *Vifor* case, which was concluded with a commitment decision in July 2024. Vifor was found to have potentially abused its dominant position by spreading misleading information about the safety of a rival drug to its own product, Ferinject. Kaup emphasised the scale of the communication campaign Vifor must now undertake to remedy the harm caused. This includes issuing clarifying communications to healthcare professionals, publishing the corrections on Vifor's website and in medical journals, and allowing third parties to use this communication to provide accurate information.

[4] *Teva Copaxone* (Case AT.40588) Commission Decision [2024].

[5] European Commission, Press Release 'Commission Opens Investigation into Possible Anticompetitive Conduct by Zoetis over Novel Pain Medicine for Dogs' (26 March 2024) <https://ec.europa.eu/commission/presscorner/detail/en/ip_24_1687>.

The second speaker to take the floor was Wolf Sauter, Professor of Law, Markets and Behavior at Vrije Universiteit of Amsterdam and coordinating specialist enforcement official at the Dutch Authority for Consumers and Markets (ACM). His presentation focused on the Dutch *Laediant*[6] case, a national case concerning excessive pricing which has already been decided by the Dutch Competition Authority and is awaiting the judgment of the court hearing it. The case concerns an exploitative abuse of a dominant position, namely excessive pricing. Sauter provided context for this case by describing the Dutch private health insurance system, which is built on mandatory affiliation and competition among private insurance companies which compete to secure favourable contracts with healthcare providers. A unique aspect of the Dutch healthcare system is the concentration of specialised care for rare diseases, despite the fully private nature of the system. In the *Laediant* case, the pharmaceutical company is accused of setting excessively high prices for an orphan drug, a medicine designed to treat rare diseases which receives regulatory exclusivity for an additional 10 years as a reward for the investment in developing a treatment for these specific needs. A series of price increases for Leadiant's drug led to the excessive pricing case. In July 2021, the Dutch Competition Authority fined Laediant based on the *United Brands* principles, which assess whether high prices are justified by costs. Specifically, the Authority found that Laediant's prices were unfair based on the following considerations: the lack of innovation or therapeutic added value, since the drug had only been repurposed from an existing treatment that had been used off-label since the 1970s; the lack of alternatives on the market; and the exorbitantly high level of prices. The Dutch Competition Authority also rejected Laediant's objections and its proposed commitments in 2023, taking a strong stance to clarify that excessive pricing in the pharmaceutical sector can be applied even to orphan drugs, not just off-patent pharmaceuticals serving large markets. Sauter also referred to the appeal concerning the pharmaceutical preparation, the case about the lack of transparency of Laediant's communications and statements, and the alleged boycott of health insurers in the Dutch context. He also mentioned

[6] ACM, Case No ACM/20/041239 (2021).

cases in other countries, including one in Italy[7], where, in March 2024, the Council of State upheld the fines imposed on Laediant for excessive pricing, and one in Spain[8], where Laediant was fined in 2022. Sauter observed that excessive pricing cases are generally rare, largely due to the significant time and resources required by competition authorities to prosecute them. One challenge in these cases is that the price-cost differentials are often not large enough to justify prosecution. As an alternative approach, he suggested considering excessive pricing cases as unfair trade practices, which might be easier to prosecute due to the lower standard of proof required, greater flexibility, and more options for addressing the issue. He also pointed out that these cases are typically of greater interest to national competition authorities than to the European Commission. In his opinion, this highlights the need for clear guidance from the European Commission on exploitative abuses. In his concluding remarks, Sauter emphasised the importance of finding a balance between competition and regulation in fostering innovation. He questioned whether the newly-proposed EU pharmaceutical legislation[9] adequately strikes that balance.

While the previous presentations focused on antitrust issues that have emerged in past and more recent years, Luca Arnaudo, senior officer at the Italian Competition Authority (AGCM) and distinguished lecturer at Syracuse University, turned the discussion towards potential future scenarios in pharmaceutical antitrust enforcement, particularly cases that have yet to emerge but could become relevant in the coming years. Arnaudo focused on combination therapies, which he defined as the use of two or more therapeutic agents together (not necessarily active pharmaceutical ingredients,

[7] Italian Council of State, Judgment No 2967 of 29 March 2024.

[8] CNMC, Case No S/0028/20 (2022).

[9] The 'Pharmaceutical Package' put forward by the European Commission to revise the EU's pharmaceutical legislation includes the following: Commission, 'Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006' COM(2023) 193 final; Commission, 'Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC' COM(2023) 192 final; Commission, 'Proposal for a Council Recommendation on stepping up EU actions to combat antimicrobial resistance in a One Health approach' COM(2023) 191 final.

but also different drugs) to enhance treatment efficacy. He provided historical examples, starting with combination therapies for tuberculosis in the 1950s, followed by the highly effective combinations for HIV treatment in the 1990s. Today, combination therapies are also used for treating certain types of cancer and have recently been used for the treatment of COVID-19 cases. From a competition law perspective, Arnaudo explained that combination therapies present unique challenges due to the peculiar nature of these products, that is, the fact that they mix products. He raised concerns about potential abuses of dominant position, such as tying (when a company with significant market power in one market requires customers to purchase also a second product) and bundling (the practice of selling multiple products together as a package). These practices, while potentially beneficial to consumers in terms of lower prices and greater ease of use, can also be strategically employed to leverage market power. In the case of combination therapies, they can allow the implementation of complex strategies that may lead to higher prices and delayed market entry of more affordable treatment options. Although no case law has yet emerged in Europe regarding combination therapies, Arnaudo referred to two recent developments in the United States and the United Kingdom. In the US, he highlighted a stream of antitrust litigation involving major pharmaceutical companies and the antiretroviral fixed-dose combinations (FDC) for HIV treatment. The companies were accused of collusive behaviour aimed at maintaining high drug prices and blocking generic competition by preventing the combination of originator and generic components in FDC drugs. This case was eventually settled. Arnaudo also highlighted important questions raised by combination therapies in terms of market definition, asking, for instance, whether the relevant market should be defined by the disease being treated or as a single product market. He also referenced an Amicus Curiae Brief by the Federal Trade Commission on the issue. Turning to the UK, Arnaudo discussed the 2023 *Prioritisation statement on combination therapies*[10] issued by the Competition and Markets Authority (CMA). This *Statement* reflects a cooperative solution, largely pushed by UK pharmaceutical producers. According to the *Statement*, antitrust investigations into the development of combi-

[10] CMA, *Prioritisation Statement on Combination Therapies* (17 November 2023) <https://assets.publishing.service.gov.uk/media/6554fd97d03a8d001207f9f9/Prioritisation_statement_on_combination_therapies.pdf>.

nation therapies would not be prioritised, provided pharmaceutical companies do not cross certain 'red lines'. This approach recognises the public policy value of incentivising innovation in this field, while also acknowledging concerns over the limited availability and high prices of such therapies. Arnaudo also raised concerns about consumers' aversion to complexity, which may encourage pharmaceutical companies to use bundling strategies. These strategies could confuse consumers, causing them to pay higher prices for treatments, and to lack clarity on what they are paying for. As a final consideration, Arnaudo praised initiatives like the CMA's *Statement* as an example of effective collaboration between stakeholders, ie, industry, competition authorities, and medicine agencies. He emphasised that this kind of cooperative approach is essential for supporting innovation while addressing the challenges posed by combination therapies. He also noted that such a collaborative framework may be more effective than pricing schemes, like the one used in Germany, in addressing these issues.

The session on antitrust law concluded with a speech by Patrick Actis Perinetto, counsel at Chiomenti law firm. Perinetto's presentation centred on the assessment of innovation in competition law, using pharmaceutical mergers as a case study. He began by emphasising the growing significance of innovation in recent years, noting that it has become an essential factor across all industries and sectors. Innovation, he argued, has shifted from being one of many competitive parameters to the dominant parameter of competition. It has become a game-changer, influencing which companies can compete in the market and reshaping the concept of the relevant market by interconnecting areas that were once distinct. Perinetto then examined the dual impact of mergers on innovation. Mergers can enhance innovation by creating efficiencies and synergies, but they can also stifle it. He explained that mergers might lead to the discontinuation, delay or redirection of a merging party's innovation efforts, as well as the elimination of competition between the merging companies. This, in turn, can have broader spillover effects on the entire market, diminishing overall market incentives to innovate. Acknowledging the unique characteristics of the pharmaceutical sector – such as the high cost, lengthy process, and inherent uncertainty of research and development (R&D) – Perinetto argued that the pharmaceutical industry provides an ideal case study for assessing innovation in competition law. The challenges of innovation are particularly pronounced in this sector, making it a critical area for understanding how competition

law can address innovation. He concluded that resolving innovation-related issues in the pharmaceutical sector could help address similar challenges in other sectors. Perinetto also recognised that assessing innovation poses challenges because it lacks some of the traditional features of competition law analysis. Innovation is dynamic, difficult to measure, often lacks sufficient data, and is characterised by uncertainty and a lengthy assessment process. However, he contended that many of these issues are not new to competition law. The criticisms surrounding the application of competition law to innovation are, in his view, misplaced. He further pointed out that, in the pharmaceutical sector, the issue of the lack of data is somewhat alleviated by the structured R&D process, which generates more data than in many other sectors. This, in turn, helps mitigate some of the challenges involved in evaluating innovation. Perinetto concluded that the European Commission's decisional practice in pharmaceutical mergers, where most innovation-related cases in competition law arise, demonstrates that competition authorities are well-equipped to handle innovation-related issues effectively. He highlighted the European Commission's clear, structured, and effective framework for assessing innovation, which he believes could serve as a model for developing a broader approach to innovation in competition law. In his concluding remarks, Perinetto warned that competition law is ultimately about protecting competition, not innovation for its own sake. While innovation and competition often go hand in hand, they can sometimes lead to opposing conclusions, and it is important to balance the two in antitrust assessments.

The first speaker in the second session was Fiona Macmillan, Professor of Commercial and Intellectual Property Law at Roma Tre University, who presented a revised perspective on the traditional patent bargain. The pharmaceutical sector, she noted, is one of the most profitable industries in the world, and the patent system plays a critical role in its business model (ie, its profitability). This can be seen in the pharmaceutical industry's active involvement in patent-related negotiations and lobbying efforts, such as the influence exerted during the TRIPS Agreement negotiations, lobbying at the EU level for patent term extensions, and significant involvement in debates over the efficacy of the patent system. Two notable incidents illustrating these efforts are the controversies surrounding access to anti-AIDS retrovirals in sub-Saharan Africa and the COVID-19 vaccines, both of which prompted lobbying,

for patent waivers and an extension of such waivers, respectively. Macmillan outlined the traditional patent bargain: pharmaceutical companies invest in research and innovation, publicly disclose their findings, and, in return, receive a monopoly over the innovation for at least 20 years. While this system benefits the pharmaceutical industry, she questioned whether these benefits align with societal needs. She argued that under this version of the patent bargain, the focus is more on supporting the business model of pharmaceutical companies rather than delivering social benefits. This imbalance is evident in the sector's very substantial returns, in the innovation quality and efficacy, as well as in the nature of the knowledge produced, which often originates from previously public domain knowledge or from non-Western communities. Macmillan further argued that the patent system functions not only as a business model but also as a social model, capable of delivering broad societal benefits such as encouraging innovation, improving public health outcomes, and ensuring affordability and access. However, she discussed various critical aspects of the patent-based pharmaceutical system, highlighting several issues. For instance, the pricing and distribution of patented medicines came under scrutiny during the humanitarian crisis surrounding access to anti-AIDS retrovirals in sub-Saharan Africa. Additionally, the system distorts research priorities by driving pharmaceutical companies to focus on lucrative markets, primarily in the West, while neglecting diseases that affect developing countries. Similarly, COVID-19 vaccines revealed disparities in access, especially in the developing world, highlighting issues of availability. As further distortions arising from the patent system, she mentioned the following: the enclosure of publicly available knowledge once a patent is granted, which can limit further research; a focus on research aimed at avoiding patent infringement rather than addressing genuine medical needs; the risk that research may not target new medical threats but merely replicate existing studies; the spending of significant portions of pharmaceutical profits on marketing to reduce demand elasticity, rather than on funding new research; the high transaction costs associated with the patent system that further divert resources away from innovation. Using the example of COVID-19 vaccines, Macmillan explained how their development and distribution in Western countries were largely the result of public funding. Much of the foundational research was conducted in publicly funded institutions and transferred to pharmaceutical companies, which then produced the vaccines rapidly. In return, the only benefit to the

public was preferential access to the vaccines. This resulted in costs to the public purse and profits in the form of dividends for the shareholders of pharmaceutical companies. Macmillan raised concerns that this situation, whereby much of the research resulting in innovation is made in public institutions and subsequently transferred to the private sector, might lead to public research starting mimicking the priorities and distortions of pharmaceutical companies. Macmillan also discussed how the pharmaceutical industry has responded to criticisms in the post-COVID era. The industry has increasingly aligned itself with the pro-science discourse, particularly in opposition to the anti-science, anti-knowledge no-vax movement. This shift has allowed pharmaceutical companies to frame their interests, and the patent system, as aligned with broader scientific and societal goals. By doing so, the industry has distanced itself from traditional justifications for patents and instead argued that profits derived from patents enable further research that could address future health crises, such as pandemics. In her concluding remarks, Macmillan, while acknowledging that patents remain crucial for funding research, argued that their role in the system of innovation should be reconsidered.

The next speaker was Daria Kim, Senior Research Fellow at Max Planck Institute for Innovation and Competition, who addressed the role that artificial intelligence (AI) could play in shaping the future of the pharmaceutical industry. Her talk covered both AI's potential impact on drug discovery and development, as well as how AI could lead to a rethinking and restructuring of the innovation incentives system and the patent bargain. Kim began by exploring the potential of AI in drug discovery. While some perspectives highlight AI's revolutionary potential, promising substantial benefits, more cautious views temper such optimism. Kim shared a balanced position, acknowledging that AI could indeed improve the efficiency of drug research. However, she pointed out that quantifying the extent of these efficiencies, such as how much AI could reduce the cost of drug R&D, remains challenging. She also suggested that the development of personalised medicines, while a promising prospect, is still more of a future possibility than a current reality. Turning to the implications of AI on innovation incentives, Kim addressed diverging opinions, including the extreme view that AI could lead to the abolition of the patent system. In contrast, she argued that AI is unlikely to result in revolutionary changes to the incentive system. At best, it might bring about

some changes to the patent system. In her view, AI primarily helps to highlight and address the inherent tensions within it. Kim identified several key tensions within the current patent system, starting with its insensitivity to efficiencies. She explained that the patent system does not correlate R&D investment with the reward granted, meaning that reduced R&D costs through AI are unlikely to result in lower prices for consumers. Making also reference to the recent EU pharmaceutical reform, she concluded that the intellectual property system only becomes sensitive to the costs of innovation when there is a perceived lack of incentives. The second tension she discussed was the patent system's insensitivity to exclusivity alone. While patents do improve the competitive advantage of innovators, Kim noted that true innovation arises from a combination of technological and market opportunities and pointed out that many recent advancements were not driven solely by patents. With regard to the EU pharmaceutical reform, she noted that it targets cases where innovation incentives are lacking, but still primarily relies on exclusivity, while, in her view, there is a need to also address technological opportunities as factors behind patent system failures. Next, Kim discussed the insensitivity of the patent system to social value. The system, she argued, is based on a rational actor theory, where innovators seek to maximise their own utility, which does not always align with the maximisation of collective utility. This misalignment means that innovators may prioritise patentable inventions over those that offer greater social or public health value. In this context, AI's potential lies in its ability to drive personalised medicine, which could better meet societal needs. Connected to this is the insensitivity of the patent system to the social cost it generates. Kim noted that the patent system not only prioritises market value over social value but also leads to social costs, particularly in the form of supra-competitive pricing derived from restricted competition, irrespective of the efficiencies generated. In conclusion, Kim argued that while the patent system purports to balance social costs and benefits, in practice, finding a workable balance is difficult. Moreover, the insensitivities and imbalances inherent in the current patent system could be exacerbated by disruptive AI technologies in innovation. She expressed concern that the new EU pharmaceutical reform is unlikely to address these issues effectively.

The discussion continued with a presentation by Enrico Costa, Head of International Affairs Department of the Italian Medicines Agency, who discussed the

new proposed reform of the EU pharmaceutical legislation. He provided an overview of the main elements of the reform, as well as the challenges and concerns that may arise from them. The proposed reform consists of a new Regulation, a new Directive, and a Council Recommendation on antimicrobial resistance (AMR). Costa began by outlining the objectives of the European Commission's proposal, which include ensuring timely and equitable access to medicines for EU patients, attracting R&D investments in an innovation-friendly environment, enhancing the security of the supply chain (the importance of which was highlighted by the COVID-19 pandemic), and improving the environmental sustainability of medicines. The first point Costa addressed was market protection. He noted that the EU is among the global leaders in data and market protection, with a standard period of 8+2 years. However, the European Commission's proposal aims to shift to a more flexible approach, reducing the base period of protection to 6 years. This period could be extended if certain outcomes are met by the applicant, such as the marketing of the new medicinal product in each EU Member State (though this provision was later removed by the European Parliament). Next, Costa discussed the proposed amendments to regulatory protection in the orphan drug space. The European Commission's proposal involves a reduction and modulation of market exclusivity protection, with adjustments based on meeting specified goals. He expressed concerns regarding the vagueness of certain terms, such as 'high unmet medical need', which could complicate their interpretation and potentially hinder price negotiations at the national level. Costa also mentioned the introduction of transferable data exclusivity vouchers, designed to incentivise R&D in antibiotics. While he acknowledged their potential, he highlighted the challenges posed by the unpredictability in their use and of when a medicine would enter the market, making these vouchers a less reliable form of funding. A further (indirect) way of prolonging exclusivity, Costa suggested, could be to streamline the approval process for medicinal products. This could help accelerate market access and extend the exclusivity period for innovators. He then turned to other aspects of the proposal, particularly those concerning generics and biosimilars. He noted that the Bolar exemption (ie, the provision which permits the use of patented medicinal products to conduct the necessary studies and trials required for obtaining market authorisation for generic and biosimilar drugs prior to the expiration of the patent or supplementary protection certificate, exempting such

otherwise infringing activities from patent infringement liability) would be both broadened and more clearly defined in order to align the behaviour of all EU Member States in this area. Additionally, the proposal eliminates the requirement for risk management plans for generics and extends regulatory data protection for off-patent medicines repurposed for new uses. In his concluding remarks, Costa emphasised that, despite the pharmaceutical market being the most regulated in the world, regulation alone is not the solution to all the challenges in the sector. He noted that, while additional protection for the most effective drugs may be beneficial, it is ultimately the market that will determine the return on investment for game-changing innovations.

The next speaker was Carlo Riccini, Deputy Director General, Research Center Directorate of Farmindustria, who provided valuable insights from the perspective of the pharmaceutical industry on the role of regulation and policy. Riccini began by emphasising that regulation should not only focus on competition but also on competitiveness, which he defined as the ability to attract and retain investments. He noted that pharmaceutical innovation today, and increasingly in the future, reflects a blend of scientific progress, technological advancements, and societal needs. He presented the pharmaceutical industry as Europe's leading high-tech sector in terms of R&D, exports, and imports. However, he highlighted a significant concern: compared to countries like the US, the EU lags behind in investment and innovation. Riccini pointed out that the US is investing considerably more than the EU, with innovation advancing more rapidly, partly due to the simpler regulatory environment in the US. Over the past five years, the US has been actively implementing policies to attract investments, while China has also seen rapid growth as both an R&D user and producer. This, he argued, places the US and China ahead of the EU in pharmaceutical sector innovation. Using clinical trials as an example to explain the point, Riccini stressed that if the EU loses its competitiveness, this will negatively impact public health, leading to reduced care and fewer resources. He also pointed out a strategic mistake made by both the EU and the US, namely their dependency on China and India for pharmaceutical active ingredients. Given these challenges, Riccini emphasised the urgent need for the EU to become more competitive. He argued that good rules are essential to increasing competitiveness and, without them, the EU risks becoming merely a market for pharmaceuticals rather than an industry. This, he warned, would lead to significant

weaknesses with serious repercussions. Turning to the proposed reform of the pharmaceutical legislation, Riccini expressed concerns about its potential impact on EU competitiveness. He argued that the new rules could actually undermine competitiveness rather than enhance it. Specifically, he criticised the European Commission's proposal on data protection, which he felt imposes excessive conditionality on the increase in such protection. According to Riccini, investments thrive on certainty, not uncertainty, and complexity often deters investment. In his closing remarks, Riccini reiterated that competition cannot be considered without also focusing on competitiveness. He emphasised that the attractiveness of investments primarily depends on intellectual property rights, which he believes are non-negotiable for investors, at least for now. Instead of focusing on making expenditures more efficient through regulatory changes impacting on such elements, he suggested that efficiency could be achieved through policies based on honest and comparable data derived from industrial analysis.

The concluding speech of the second session was delivered by Flaminia Aperio Bella, Associate Professor of Administrative Law at Roma Tre University, who presented the implications of applying the so-called One Health approach to pharmaceutical regulation. She began by introducing the concept of One Health, which values the interrelationship between human, animal, and environmental dimensions in addressing health. She traced its historical evolution, noting that the idea originated in the early 20th century. However, the formal shift from One Medicine to One Health occurred in 2004, following a conference held after the SARS epidemic, which led to the development of the '*Manhattan Principles*', a scientific manifesto for the One Health approach. This concept was further consolidated in 2010 with the creation of a tripartite partnership between the World Health Organisation, Food and Agriculture Organisation, and World Organisation for Animal Health. In 2021, the United Nations Environment Programme joined the partnership, which became a quadripartite alliance, and the One Health High-Level Expert Panel was established to unify the concept. After the COVID-19 pandemic, One Health expanded its scope to address climate change and increasingly involved social sciences and legal disciplines, thus becoming part of the broader public, political, and legal discourse. Aperio Bella emphasised that One Health is more of a methodology than a mere concept. Key elements, as outlined

by the Expert Panel, include the equal importance of the three dimensions (human, animal, and environmental health), the shift from focusing solely on disease to a broader understanding of well-being, the expansion of the scope of application, and its clear connection to sustainable development. She highlighted that One Health is widely recognised at both the international level, particularly in pandemic prevention, and within the EU, where it is increasingly integrated into legislative frameworks, not just policy documents. Focusing on the EU pharmaceutical reform, Aperio Bella illustrated how One Health plays a central role in the proposed Directive and Regulation. One Health is one of the six main pillars of the EU Pharmaceutical Strategy, particularly in the fight against AMR and in making medicines more environmentally sustainable. She noted that all three dimensions of One Health are involved in addressing AMR, with the environment playing a crucial role in the development and spread of AMR. This necessitates action to address pharmaceutical waste and the entire lifecycle of medicines. Accordingly, as part of the reform, the environmental risk assessment of pharmaceuticals has been strengthened. Aperio Bella then compared the EU4Health Regulation[11], which is one of the most advanced examples of the One Health approach, with the EU Pharmaceutical Strategy. She pointed out that while the Pharmaceutical Strategy acknowledges One Health, it lacks a clear definition of the approach and does not explicitly link it to the accessibility and affordability of medicines or the organisational aspects of One Health. However, she highlighted the creation of a cross-agency One Health Task Force, which brings together the technical expertise of five EU regulatory agencies, including the European Medicines Agency, to implement the One Health approach. She concluded by noting that while there are multiple ways to implement One Health within the EU, two key approaches, namely using One Health as a guiding principle and as an organisational method, are already present in the EU Pharmaceutical Strategy. She also suggested that further implementation of the One Health approach in pharmaceutical regulation is possible, but it will depend on the seriousness with which the concept of sustainability, particularly its social dimension, is embraced, as equity lies at the heart of One Health. In conclusion, Aperio Bella provided a brief

[11] Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027, and repealing Regulation (EU) No 282/2014 [2021] OJ L107/1.

presentation of a draft convention on pandemics, developed by a group of lawyers formed within the framework of the International Center for Comparative Environmental Law (CIDCE), of which she was a member, emphasising the application of the One Health approach to advance the innovative concept of 'vaccine equity'.

Vincenzo Zeno-Zencovich, Professor of Comparative Law at Roma Tre University, concluded the conference by emphasising the interconnectedness of antitrust, intellectual property, and regulation. He argued that these three areas should not be viewed in isolation but as different paths leading toward the same goal: regulating something, here the pharmaceutical sector. Given the interrelated nature of these aspects, Zeno-Zencovich advocated for a comprehensive, holistic approach to regulation, one that integrates all these components. He asserted that such an approach is necessary to simplify the complexity and bring order to the often-chaotic landscape of regulation at various levels. Without this, he warned, regulation risks becoming a source of bureaucracy rather than fostering efficiency and innovation.