



Centre for Sustainability
and Corporate
Governance Research
INDIAN INSTITUTE OF MANAGEMENT AHMEDABAD

विद्याविनियोगादिकासः

SEMINAR SUMMARY REPORT

Balancing IP and ESG in Healthcare Sector

December 05, 2024



by



Prof. Srividhya Ragavan

Professor of Law & Director
International Legal Program, Texas A&M School of Law

Moderator:

Prof. Saravanan A

Assistant Professor, Strategy Area, IIM Ahmedabad



Seminar on
**Balancing IP and ESG in
Healthcare Sector**



by
Prof. Srividhya Ragavan
Professor of Law & Director of International Programs
Texas A&M University School of Law

Moderator: Prof. Saravanan A, Assistant Professor of Strategy, IIMA

December 5, 2024 **4:00 p.m. IST**

SR 13, AB-2, New Campus

Scan to
Register



<https://www.linkedin.com/company/cscgr/>

https://x.com/CSCG_IIMA

Table of Contents

About the Speaker	01
About the Moderator	02
Abstract	03
Introduction	04
Seminar Summary	05
Q&A Session	08
Key Takeaways & Conclusion	10
Acknowledgements	11



About the Speaker



Prof. Srividhya Ragavan

Srividhya Ragavan specializes in Intellectual Property, Patents, Trade focusing on the interdisciplinary perspectives of intellectual property and its implications on health. She is currently a Professor of Law & Director, International Legal Program, Texas A&M School of Law. Her research brings together three distinct areas of expertise: (a) access to medications and health; (b) intellectual property; and (c) trade and development. She is also a member of the law school's top-ranked Center for Learning Intellectual Property Rights.

Srividhya has published 6 books, 100 law review articles, book chapters, and policy reports. She sits on the editorial board of several interdisciplinary and scientific journals in Asia, Europe and Canada. She serves in leadership roles in several professional organizations, including the Association of American Law Schools, the International Law Association and the Research and Information System for Developing Countries. Sri regularly advises national governments and international organizations on issues related to Intellectual Property and International Trade. She is an expert for the World Intellectual Property Organization, the World Health Organization and the World Trade Organization. Ragavan has testified at the U.S. International Trade Commission (USITC) as well as before the Office of United States Trade Representative (USTR).



About the Moderator



Prof. Saravanan A

Saravanan A is currently working as Assistant Professor in the Strategy Area at IIM Ahmedabad. He completed his LLM from Symbiosis Law School, Pune, followed by a PhD in International Investment Law from IIT Kharagpur in 2018. His teaching and research interests lie in the areas of international investment law, intellectual property law, energy policy, and business law.



Abstract

The presentation will focus on whether and if so, how the need for innovation, protection and regulation in the healthcare sector can be balanced with the responsibilities of ESG requirements. The monopoly component of a patent consists of the right to prevent competition and to charge a maximum market price. In gist, intellectual property (IP) rights are market incentives for patentees to derive maximum economic efficiency divorced from the concept of welfare. In contrast, Environmental, Social, and Governance (ESG), focuses on sustainability from an ethical, responsibility framework. Thus, there is a natural tension between the area of law that improves the corporate bottom line by securing exclusionary monopoly rights with a core principle that focuses on the inclusive welfare possibilities of innovation and its by-products. Navigating these cross-roads will be a challenge for policy makers, industry and ultimately, the corporate board, which will be the focus of the presentation.



Introduction

The rapidly evolving nexus between intellectual property (IP), healthcare, and global sustainability has become a focal point for policymakers, corporations, and academics alike. In this context, the seminar delivered by Professor Srividhya Ragavan provided a timely and insightful examination of these complex intersections. Hosted by the Center for Sustainability and Corporate Governance Research (CSCG), the seminar addressed pressing issues such as the role of IP in global trade, its implications for healthcare equity, and the integration of Environmental, Social, and Governance (ESG) principles into policy frameworks. By leveraging real-world examples and her vast expertise in intellectual property law and patent regulations, Professor Ragavan unpacked the nuanced challenges and opportunities within this domain, advocating for transformative policy changes and collaborative action.

The seminar's overarching theme revolved around reimagining IP as a tool that transcends its traditional confines of incentivizing innovation. Instead, Professor Ragavan argued for an IP framework that harmonizes with ESG objectives, ensuring that innovation not only fosters economic growth but also addresses societal needs and promotes global equity. This perspective is particularly pertinent in the wake of the COVID-19 pandemic, which exposed the vulnerabilities of global healthcare systems and underscored the urgent need for resilient and equitable solutions.

This report captures the essence of Professor Ragavan's discourse, delving into critical areas such as patent systems, the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, the potential of artificial intelligence (AI) in drug development, and the environmental impacts of pharmaceutical production. Through an in-depth exploration of these topics, the report aims to shed light on the transformative potential of aligning IP practices with sustainability and equity goals, offering actionable insights for stakeholders across sectors.



Seminar Summary

Professor Srividhya Ragavan offered an exciting yet profound exploration of the intricate intersections between intellectual property (IP), Environmental, Social, and Governance (ESG) considerations, and public health. She began her discourse by highlighting the evolving and sometimes conflicting roles of IP in the global landscape, with particular emphasis on its implications for healthcare equity, international trade dynamics, and policy formulation. Speaking from the standpoint of patents, which is her area of expertise, Prof. Ragavan delved deeply into the critical themes that are currently driving the world of IP in healthcare and provided actionable recommendations that need to be adopted to overcome the challenges of this sector.

At the heart of the seminar was a thorough and acute critique of intellectual property as a double-edged sword in modern society. According to Professor Ragavan, originally, patents were conceived as mechanisms to incentivize creativity and innovation by offering inventors exclusive rights for a limited period, based on the idea that they would ultimately be a public good. This design was intended to strike a balance between rewarding innovation and ensuring public access to its benefits. Over time, however, the role of patents has shifted dramatically, transforming into potent commercial tools that often prioritize profit over public welfare. Professor Ragavan likened patents to "barren lands", which are inherently unproductive but can be strategically exploited to generate significant monetary value, such as by building houses and renting or grazing cattle. This metaphor underscores the complex dichotomy of patents: while on one hand they can serve as powerful enablers of creativity and innovation, on the other hand they can also function as formidable barriers that restrict access to essential technologies and medications. This conflict between the idealized purpose of patents and their real-world applications formed a recurring theme throughout the seminar.

Contextualizing the issue with global developments, Professor Ragavan spoke of the "flawed romance" between patents and trade. She began a particularly

illuminating discussion focused on the World Trade Organization's (WTO) Agreement on TRIPS. Describing TRIPS as emblematic of the aforementioned relationship of patents with trade, Professor Ragavan critiqued the agreement's prioritization of trade and economic gains over public health. The agreement, originally intended to harmonize IP standards globally, has inadvertently exacerbated inequities between nations, with pharmaceutical patents having largely reset the global trade agenda. Developing countries, already grappling with fragile healthcare systems, have borne the brunt of this misalignment. She argued that the COVID-19 pandemic starkly exposed these glaring vulnerabilities, as global supply chains faltered and countries struggled to access critical vaccines and medications. The pandemic underscored the interconnectedness of trade, health, and productivity, highlighting the urgent need to reevaluate the role of TRIPS in shaping global health policies.

Professor Ragavan then moved on to explain the integration of ESG principles into IP practices, which has emerged as a pivotal theme in the global scenario. She emphasized that public health needs to become a cornerstone of ESG considerations, encompassing dimensions such as health equity, access to essential medications, and the resilience of healthcare supply chains. She argued that effective policy making is the linchpin of these efforts, advocating for legislative frameworks that align IP practices with the broader goals of sustainability, equity, and innovation. Such policies, she noted, should bridge the gap between the protection of intellectual property and the equitable distribution of its benefits, ensuring that, in the end, innovation serves the collective good.

A significant challenge discussed was the pricing and accessibility of essential medications. Patent regimes, by granting exclusivity, often lead to inflated drug prices, making lifesaving treatments inaccessible to vulnerable populations. Professor Ragavan cited the AIDS crisis as a poignant example. As the crisis metamorphosed into an acute global health concern, countries like Brazil and South



Africa tapped into the provisions and flexibilities offered by TRIPS, such as compulsory licensing, to manufacture generic versions of antiretroviral drugs, significantly lowering costs and expanding access. However, despite the success of these measures, they faced staunch opposition from multinational pharmaceutical companies and trade bodies. The case of AIDS and its role in shaping the understanding of public health dynamics underscores the necessity of advocating for broader and more equitable applications of TRIPS flexibilities to address public health emergencies effectively. Such measures, she argued, are not just legal provisions but moral imperatives in the face of global health crises.

The seminar also highlighted the critical importance of local manufacturing in building resilient healthcare systems. Restrictions imposed by the TRIPS framework on the local production of patented drugs have created significant barriers for many countries. Professor Ragavan discussed the example of India's efforts to manufacture COVID-19 vaccines, which were hampered by both legal and logistical challenges. Similarly, the United States' insulin crisis underscored the need for localized production capabilities to ensure affordability and accessibility. Local manufacturing, she argued, not only addresses supply chain vulnerabilities but also fosters innovation, self-reliance, and economic development. By enabling countries to produce essential medications domestically, such policies reduce dependence on global supply chains and enhance their capacity to respond to health emergencies. Additionally, localized production can stimulate job creation and the development of technical expertise, further contributing to regional economic growth.

The discussion further extended to the regulatory barriers that delay the market entry of affordable alternatives such as generics and biosimilars. Referring to the system in the US, in particular, its regulatory landscape, characterized by prolonged exclusivity periods and the intricate "patent dance" process, has become a significant obstacle. The discussion extended to the regulatory barriers that delay the market entry of affordable alternatives like generics and biosimilars. One of the most intricate and often misunderstood regulatory processes

discussed was the "patent dance," a term that refers to the structured litigation and negotiation process under the Biologics Price Competition and Innovation Act (BPCIA) in the United States. The patent dance is designed to address disputes over biosimilars, which are highly similar, near-replicas of biologic drugs. While intended to create a framework for resolving patent conflicts efficiently, the process has often proven cumbersome and time-consuming.

Spanning over 245 days, the patent dance involves a series of steps, beginning with the biosimilar applicant providing the original biologic manufacturer with its application and manufacturing details. This initiates an exchange of patent lists and statements, where both parties identify which patents are believed to be infringed upon and whether they are valid. Following this exchange, the process often leads to multiple rounds of litigation. While this system is meant to foster transparency and predictability, it has been criticized for delaying the market entry of biosimilars. Innovator companies frequently use the patent dance to erect additional barriers, prolonging exclusivity periods and stifling competition.

Professor Ragavan explained that the inefficiencies of the patent dance are compounded by the complexity of biologics themselves, which are typically more challenging to replicate than traditional small-molecule drugs. These challenges make it easier for original manufacturers to claim patent infringements on various aspects of biosimilar production, from the manufacturing process to molecular composition. Consequently, the patent dance has become less about resolving disputes efficiently and more about delaying the inevitable entry of more affordable biosimilars into the market.

The implications of the patent dance are profound, particularly for healthcare systems in need of cost-effective alternatives to expensive biologic drugs. Professor Ragavan argued that reforming this process is imperative for ensuring that biosimilars can reach patients more quickly. Some of the potential solutions, she postulated, include streamlining the procedural steps, limiting the scope



of litigation, and incentivizing quicker resolutions through arbitration or mediation. Without such reforms, the patent dance risks undermining the very goals it was intended to achieve, perpetuating inequities in access to essential medications.

Professor Ragavan argued that while these barriers are ostensibly designed to protect innovation, they often exacerbate inequities in healthcare access. She called for comprehensive reforms to streamline approval processes, reduce exclusivity durations, and eliminate unnecessary bureaucratic hurdles. These reforms, she noted, are particularly crucial for countries like India, where adopting the litigation-intensive American model would be both impractical and counterproductive.

Environmental considerations also featured prominently in the seminar. Professor Ragavan highlighted the pharmaceutical industry's substantial environmental footprint, calling for sustainable manufacturing practices that align with global climate goals. She discussed the importance of adopting cleaner production techniques, utilizing renewable energy sources, and ensuring the responsible disposal of chemical waste. These measures, she argued, are not just environmental imperatives but also essential components of corporate social responsibility (CSR). By aligning their operations with ESG principles, pharmaceutical companies can enhance their social license to operate and contribute to broader sustainability goals.

A recurring theme was the transformative potential of artificial intelligence (AI) in healthcare. Professor Ragavan described AI as a game-changer for the pharmaceutical industry, offering opportunities to accelerate drug discovery, optimize clinical trials, and reduce development costs. However, she also cautioned against the ethical and practical challenges associated with AI, including issues of data privacy, algorithmic bias, and unequal access to AI-driven innovations. She stressed the need for robust governance frameworks to ensure that AI applications are ethical, transparent, and inclusive, promoting equitable outcomes across diverse socioeconomic groups.

Global collaboration emerged as a cornerstone of Professor Ragavan's vision for a more equitable healthcare system. She pointed to successful initiatives like the Global Fund to Fight AIDS, Tuberculosis, and Malaria as models for effective resource pooling and equitable distribution. Such partnerships, she argued, demonstrate the power of collective action in addressing systemic challenges. By combining resources, expertise, and technology, stakeholders can create more resilient and inclusive healthcare systems that prioritize the needs of the most vulnerable.

Expanding the Vision: ESG, Innovation, and Beyond

Beyond immediate concerns, Professor Ragavan advocated for a more integrated approach to governance that connects intellectual property, environmental imperatives, and global equity. Pharmaceutical companies, she argued, are uniquely positioned to act as agents of change. By prioritizing ESG principles, these companies can transform not only their operational practices but also their global impact. Governments, too, must play a proactive role by introducing legislation that fosters innovation while ensuring inclusivity. Examples from Scandinavian nations, where sustainability and innovation coalesce, offer valuable lessons. These nations demonstrate that prioritizing public health and the environment need not come at the expense of economic progress.

The seminar also touched upon the potential for integrating advanced analytics and real-time monitoring into pharmaceutical governance. Tools like blockchain can enhance transparency in supply chains, ensuring that medications reach those who need them most. Such innovations, Professor Ragavan emphasized, must be accompanied by ethical oversight and cross-sector collaboration to maximize their impact.

Q&A Session

Q. What is evergreening in the context of patents?

A. Evergreening refers to the strategic practice employed by companies to extend the market exclusivity of their products beyond the standard patent duration, typically 20 years. For example, a company might file secondary patents on new formulations, uses, or byproducts of the original drug. A famous case involves Claritin, where the patent holder obtained a separate patent for a metabolite formed in the human body after ingestion. Such practices often lead to disputes, as they can delay the entry of generics into the market, impacting affordability and accessibility.

Q. How does lithium's patenting differ based on its use?

A. Lithium can be patented for its applications in different domains, such as batteries or drugs. These patents operate independently, with distinct durations and regulatory frameworks. For example, lithium used for medications would adhere to pharmaceutical patent norms, while its use in batteries would follow technological standards. Issues arise when cross-applications, such as manufacturing lithium for one purpose and repurposing it for another without proper licenses, breach patent or regulatory guidelines.

Q. Can you explain the conflict between local manufacturing and international trade obligations?

A. Local manufacturing of patented products often clashes with obligations under the TRIPS agreement. For instance, if a patented medication like Pfizer's drug is to be manufactured locally in India, the country must either obtain a voluntary license, invoke compulsory licensing (subject to WTO disputes), or rely on imports. Parallel importation, where drugs manufactured at lower costs in one region are sold in another at higher prices, complicates the situation further. This can create black markets and disrupt international trade.

Q. What role does compulsory licensing play in healthcare access?

A. Compulsory licensing allows a government to authorize the production of a patented product without the patent holder's consent, typically to address public health emergencies. India has exercised this provision in the past, notably for cancer medications. However, such actions often result in diplomatic tensions and trade disputes, as seen when the U.S. placed India under its Special 301 Priority Foreign Country list following such measures.

Q. How does external logic interact with internal IP systems in the context of universal healthcare systems?

A. External logic refers to infrastructures and policies created outside the traditional intellectual property (IP) framework to support broader societal goals, such as universal healthcare. Internal IP systems, governed by agreements like TRIPS, often set minimum standards for IP protection, focusing on trade and innovation. The interaction between these systems is limited due to divergent priorities—universal health care emphasizes access and affordability, while IP regimes prioritize innovation incentives and trade fairness. For instance, while countries could align external logic like universal healthcare systems with internal IP frameworks, these efforts often falter due to negotiation complexities. TRIPS-Plus provisions, for example, reinforce stringent IP norms, making it harder to integrate external healthcare access policies. Moreover, organizations like WIPO and WTO operate in silos, with WIPO focusing on soft IP and WTO emphasizing trade, which widens the gap between external logic and internal IP systems.

Q. What is the debate around public-funded innovations and private property?

A. Publicly funded innovations that become private property create ethical and economic dilemmas. For



example, vaccines developed with public funds during the COVID-19 pandemic were sold at high prices, limiting access. In the U.S., the Bayh-Dole Act includes provisions like "march-in rights," which allow the government to mandate price reductions. However, these rights are rarely exercised, sparking debates about equitable access.

Q. Why is the intersection of WIPO and WTO critical yet contentious?

A. The World Intellectual Property Organization (WIPO) focuses on soft IP policies, while the World Trade Organization (WTO) is trade-centric. This division leads to gaps in addressing cross-cutting issues like healthcare access. WIPO's administrative focus and WTO's trade regulations create barriers to holistic policy-making, despite potential benefits of integrating their mandates.

Q. What challenges exist for universal healthcare funding through public taxes?

A. Universal healthcare systems, like those in Brazil, require substantial tax revenues to fund innovation and healthcare delivery. In countries like India, where tax compliance is lower, allocating significant funds to healthcare becomes challenging. This limits the feasibility of publicly funded healthcare systems comparable to NIH-supported initiatives in the U.S.

Q. How do minimum standards in TRIPS agreements affect developing countries?

A. TRIPS sets minimum standards for IP protection that all member countries must adhere to. Developing nations often face pressure to exceed these standards (TRIPS-Plus) during trade negotiations, which can limit their ability to tailor IP laws to local needs, such as improving healthcare access or fostering local innovation.



Key Takeaways & Conclusion

Professor Ragavan's seminar provided a wealth of insights into the complex interplay between intellectual property and public health within the broader ESG framework. A major takeaway was the need to view patents not only as tools of innovation but also as instruments with the potential to obstruct equitable healthcare access. She highlighted how the WTO's TRIPS agreement, while intended to harmonize global trade, often prioritizes economic interests over public welfare, exacerbating healthcare disparities. The seminar also emphasized the pressing importance of integrating ESG principles into IP practices to address inequities in access to medications. Policymaking emerged as a cornerstone of these efforts, with targeted legislative changes such as enhancing TRIPS flexibilities, simplifying regulatory frameworks, and supporting local manufacturing being pivotal to ensuring healthcare equity. Furthermore, the integration of AI in drug development holds the promise of faster and more cost-effective innovation but necessitates robust ethical and data governance frameworks. Lastly, fostering collaboration among diverse stakeholders—governments, NGOs, academics, and the private sector—is essential to driving sustainable and equitable outcomes in global healthcare.

Lastly, the seminar highlighted the urgent need for a paradigm shift in how intellectual property is perceived and managed within the healthcare sector. By positioning ESG at the forefront of IP practices, stakeholders can ensure that innovation serves as a bridge to equitable healthcare rather than a barrier. The seminar underscored the interconnectedness of public health, trade, and sustainability, advocating for a holistic approach to policy making. Such an approach must prioritize health equity through regulatory reforms, foster local production to build resilience, and leverage emerging technologies responsibly. The insights shared during this seminar are not just theoretical imperatives but practical calls to action. They lay a roadmap for reimagining intellectual property as a tool for societal good, paving the way for a more sustainable, inclusive, and resilient global healthcare ecosystem.



Acknowledgements

The Centre for Sustainability and Corporate Governance Research (CSCG) would like to extend its sincerest thanks to:

1. Prof. Srividhya Ragavan for providing unique insights into the intersection between ESG and IP in the healthcare sector and how patent regulations impact the ESG landscape in this domain;
2. Prof. Saravanan A for moderating the seminar;
3. Prof. Anish Sugathan and Prof. Neerav Nagar for their support in organising this seminar;
4. PGP/PGPX/PhD students, Research Assistants/Associates (RAs), and Academic Associates (AAs) for attending;
5. Participants from the industry and academia;
6. The IIMA Communications Team for its creative and design support; and
7. The IIMA IT team for its help and logistical support.



**Centre for Sustainability
and Corporate
Governance Research**

INDIAN INSTITUTE OF MANAGEMENT AHMEDABAD

विद्याविनियोगाद्विकारः

KLMDC, Heritage Campus, Vastrapur, Ahmedabad - 380 015, Gujarat India

Prof. Anish Sugathan & Prof. Neerav Nagar | Co-Chairpersons | chr-esg@iima.ac.in

Ms. Suganya Sudhakar | Assistant Manager | am-esg1@iima.ac.in | +91-79-7152 7956