Journal of Intellectual Property Rights
Vol 29, November 2024, pp 507-515
DOI: 10.56042/jipr.v29i6.14004

Innovation Conundrum in Antimicrobial Sector: A Curious Case for Intellectual Property Rights

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Received: 27th September 2024; revised: 15th October 2024

Innovation in the antimicrobial sector has become challenging as the conventional incentive models, including intellectual property rights (IPR), fail to produce expected outcomes. Due to growing antimicrobial resistance, a persistent demand for new antimicrobials exists. However, relatively high risk and low return from the investment in antimicrobial drug development and the shorter period of use of antimicrobial drugs (as the drug of last resort) make the antimicrobial sector less attractive for investors. Moreover, antimicrobial resistance stewardship plans discourage the excessive use of antibiotics, impacting sales volumes. As a result, the limited-term monopoly of patents does not provide adequate protection for investors to recoup their investments. The R&D pipelines for antimicrobial drugs have dried up because of the reluctance among the investors and the absence of Big Pharma, and the new incentive models with a pull-and-push approach are gaining momentum. The policy interventions for antimicrobial drug development entrench between two continuums: innovation and access. The innovation structure demands novel approaches based on new/alternative incentive models at the pre-clinical and clinical stages. Patent licensing strategies could facilitate innovation and access to antimicrobial drugs, such as open and non-exclusive patent licensing and patent pooling. Given the disparities among the nations in their approach to antimicrobial resistance and antimicrobial drug development, a global health and innovation initiative with a cross-sectional and coordinated approach is pertinent. The policy interventions for antimicrobial innovation need a long-term cross-sectional and mission-oriented approach.

Keywords: Patents, Innovation, Antimicrobial Drugs, Antimicrobial Resistance (AMR), R&D

Due to specific concerns, innovation in the antimicrobial sector faces distinct challenges compared to other industries. Conventional incentive structures, including intellectual property rights, have failed to encourage the development of new antimicrobials.[1] Investors, particularly the big pharmaceutical companies, are reluctant to invest in antimicrobial sector as the research is risky and investment returns are low compared to other medicines. The R&D and innovation pipelines have dried up, which has led to new incentive models, including de-linkage and decoupling approaches, prize system, and push and pull approaches. Even within the patent system, patent licensing strategies- cross-licensing, patent pooling and patent pledges are gaining importance in the context of antibiotics. Patent licensing and collaborative agreements can play a vital role in the innovation process at the pre-clinical level, as well as in facilitating access to new or existing antimicrobial drugs. At a time when there is a shortage of new antimicrobials, particularly of new families, there is demand for extension of patent terms and repurposing of the existing antimicrobials. Open innovation can also be essential in promoting innovation and access to antimicrobials. The paper reflects the innovation conundrum of antimicrobials and the IPR-Innovation interplay in the antimicrobial sector. It highlights specific requirements of innovation in the antimicrobial sector and examines the viability of alternative approaches to innovation, focusing on innovative incentive models and push-and-pull approaches. The paper highlights the contest between innovation and access to antimicrobial drugs. It also emphasises the need for coordinated efforts at the global level, given the transnational character of antimicrobial resistance.

Innovation Conundrum of Antimicrobial Drugs

Novel antimicrobial (AM) drugs have a relatively short duration of disease compared to drugs for other chronic diseases.[2] The future market size for new AM drugs depends on how resistance changes with time.[2] Given the continual evolution of antimicrobial resistance, the need for new antimicrobials is always

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in demand. A continual pipeline is needed to provide effective treatment in the future. In its annual analyses of the pre-clinal and clinical pipeline, the WHO emphasized that 'the limited number of antibiotics in development is insufficient to address current and future needs.'[2] The dominance of only one family of antibiotics i.e. penicillin reflects the low level of innovation in antimicrobial sector. However, a growing reluctance among the big pharmaceutical companies has been noticed for several years.[3] Only Small and Medium Enterprises (SMEs) have shown their presence catching up the initial phases of antimicrobial development.

For instance, a study in the United States indicates that though the average number of patents for antimicrobial compounds have been increasing annually for the last ten years on the similar rate of patents on other pharmaceutical compounds, however, the share of commercial companies in these patents have been declined between 1990 and 2021. Universities, non-governmental organization, and governments have been catching up on the share of patent filing for these drugs. The study confirms the shift from large companies to small or mid-size companies in clinical development activities over time.[2] Despite the traces of early-stage innovation, the number of new antimicrobial drug approvals has declined between 2021 and 2023. Though the development cost of AM drugs is lower than oncology drugs however, AM drugs have low early entry market sales than the latter, which suggests that sponsors may avoid development of AM product as they are less profitable than other pharmaceutical classes.[2]

IPR and Innovation in the Antimicrobial Sector

The primary business model for pharmaceuticals consists of "covering initial R&D costs by generating downstream revenues based on high prices facilitated by monopoly power through patents."[4] This model has been struggling to produce expected outcomes due to thecomplex R&D and market structure for AM drugs. Against the bleak market for AM drugs, delinking the R&D costs from sales offers solution to this problem which entails covering the same through other means, e.g., public sector interventions, subscription models, milestone prizes etc.[5] However, the problem with the antibiotics is that despite managing R&D costs through the de-linkage models the drug stewardship limits the sale of drugs.[4] It necessitates decoupling revenues from volumes, which means "the manufacturing costs must be covered independently of the sold quantities."[4]

Patents and Innovation

The relationship between patents and innovation has remained contentious in several fields, including the antimicrobial sector. Patents have been conventionally considered as indicators of innovation; for example, the number of patents reflects how innovative the patent holder entity is. However, innovation is a multifactorial phenomenon that depends on other determinants, including economic, social, political, and cultural determinants along with policy interventions and governance. It may demand different approaches for different sectors, including biomedical and healthcare. One of the moot questions that often missed out from the mainstream discussion is 'whether patent system delivers the value that it should in healthcare'.[6] In other words, do the inventions in health care need a different approach to patenting compared to other inventions? Though the focus of the patent system is to incentivise the inventor or the patentee, yet quite often it does not create the expected economic value for patients and society. The patent structure that relies upon the fact that a patent is valuable to the degree of market probabilities for the drug has an inherent bias towards the health innovation that automatically tilt patent system more in favour of rich countries.[6]

Biomedical innovation with an academic base depends on pre-patent and post-patent collaborations. In the biomedical realm, the market for antimicrobials has been fragile. The antimicrobial sector is entrenched between two contending continuums: innovation and accessibility. The consistent failure of the existing incentive structures led to the discussion of exploring new ones with or without intellectual property (IP) protection. The fields of antimicrobial drugs and neglected drugs do not attract investors as IP incentives have yet to be able to guarantee investment returns. Although patents may not provide a viable option to encourage innovation in the antimicrobial field, it has not lost their utility, and patent licensing strategies, including patent pledges, patent buyouts, patent voucher exchanges, and open innovation models, still hold promise for biomedical innovation: "[t]he alternative patent strategies include sale, licensing and cross-licensing, patent-pooling, cooperation (alliances and joint-ventures), donation of patent rights and abandoning them, as well as deterring competitors from litigation (mutual hold up) from the point of view of the patent owner."[7] However, the literature on leveraging alternative strategies is dispersed, with little discussion on the strategic choice left to managers.[7] Nevertheless, several patent licensing strategies have been gaining significance in promoting innovation and facilitating the access to patented medicines.

Patent Pools

Patent pools become relevant when a technology is subject to several patent holders, "making it difficult for each of them to determine how to implement the technology in manufacturing without infringing or appearing to infringe on other patent holders' claims."[4] It could be a viable option to facilitate access to new medicines, including antimicrobial drugs. It permits "third parties to acquire non-exclusive licences for the intellectual property needed to develop products."[4] It has been successful in the LMICs' public health; its best example is the "Medicine Patent Pool". Patent pools offer a supportive role in promoting affordable access to novel antimicrobials, innovation, and good stewardship practices. A 2019 case study suggests that "seven new patented antibiotics were submitted for inclusion in WHO's model list in the context of WHO's new Access, Watch and Reserve categories."[8] The success of Medicines Patent Pool licences may be replicated in the antimicrobial sector to provide a mechanism that facilitates access and stewardship goals, particularly in the LMICs. It exemplifies a good model for promoting access to "affordable and appropriate medicines in LMICs by lowering prices and encouraging better-adapted formulations for resource-limited settings."[9] Based on its assessments, the WHO's expert committee projected a study that "identified five categories of products that could be potential candidates for licensing via the patent pools," including new patented antimicrobials. However, the current focus of the patent pools is "on small molecule medicines rather than bio-therapeutics, as further analysis is required to understand better the potential for patent pooling to contribute to affordable access to bio-therapeutics"[8]. The application of patent pooling to medicines, diagnostics and vaccinesmay help address the existing and future challenges.[8]

Open Innovation and Non-exclusive Patent Licensing

Open innovation in R&D strategy focuses on "sourcing knowledge and information across organisational boundaries, commonly by establishing research networks and other means of collaborative operational procedures."[4] 'Precompetitive R&D platforms', being the subset of open innovation, reflect the collaborative efforts that aim to develop technologies to overcome problems in the overall research process devoid of the intention to patent as such. The DRIVE-AB project is one of the examples of this kind, and it aims to develop an economic reward model for antibiotic innovation and stewardship. An adapted version of open source introduced by 'the Consultative Expert Working Group (CEWG) open-source drug discovery' entails "making data and papers publicly available and allowing IP rights to be used freely by collaborators (and others) by customised licenses or the use of public domain."[4] These approaches have been tested to a limited extent, and their wide implications have not been proven.

Innovation-Stewardship Conundrum

Unlike other pharmaceutical products, where prices could be controlled, and innovation could be promoted by transferring IP Rights to generic manufacturers, which ultimately contributes to universal access, the same approach could discourage stewardship efforts in the antimicrobial sector. Many proposals are gearing up to meet this situation such as patent buyouts by public entities, obligating sublicensees to adhere to "defined conservation and stewardship measures"[4]; and attaching stewardship conditions with the non-exclusive patent licenses.[10] Different models of open innovation may have led to the development of antimicrobial drugs, but an inquiry into the viability and limits of these models is pertinent, including opportunities, costs and trade-offs.[4]

Drug Repurposing for Antimicrobial Discovery

The severity of the multi-drug-resistant pathogens led to different drug discovery strategies, including drug repurposing- a process of finding new uses for existing drugs. As a new entrant in antimicrobials, drug repurposing attracts the public and private sectors. It promises the fast-tracking of compounds into clinical trials, yet it faces practical constraints that must be addressed. It has certain advantages in comparison to the new drug development from R&D and other perspectives. However, its success depends on meeting the challenges posed by the scientific, intellectual property and regulatory issues.[11] In the Indian context, Section 3(d) prohibits the new use of a known form of a substance, which excludes the economic incentives in the field of antimicrobials, yet much depends on how the claims are drafted.[12]

Innovation and Regulatory Approval

Innovation contains two aspects-technological and commercial, the former deals with "patentable technical novelty in terms of molecule" while the latter concerns with the regulatory approval for marketing (including regulator's review of manufacturer's drug-testing data).[13] Usually, the legislature requires that the manufacturer "demonstrate the quality, safety and efficacy of their product, they need not to show that the product represents the therapeutic advance in the existing therapies" unless there is a special or additional requirement for marketing approval in the legislation in this behalf.[13] Innovation in the context of drug development largely depends on the regulations imposed by the government and hence the regulatory approval is one of the main determinants of innovation.[13] In this context, data exclusivity is pitched as a viable option to prevent generic companies from freeriding, yet it encounters problems in developing countries. The patients in the LMICs are concerned about the affordability issue that is addressed by generics, and they contend that they are not against Big Pharma if the latter ~~they~~ make the branded drug available at affordable prices. However, India resists the provision of data exclusivity to secure the interest of patients through generic companies.[14]

In addition to the regulatory approvals, policy interventions also contribute to the innovation and accessibility of high-end antibiotics as "it was not only the discovery of novel drugs but the innovative approaches to science technology and health policy rendered penicillin effective, available and accessible both during and after the Second World War."[15] US Government scaled up the production of penicillin in 1940 "by modifying the policies on trade secrets, property rights, antitrust regulations, and drug licensure."[15] Therefore, incentivising innovation and ensuring global access through policy interventions is pertinent.

India's 'National Policy on Research & Development in Pharma-Med Sector in India' (18 August 2023) reflects India's dependency on the import of patented medicines despite being termed as the pharmacy of the world. The underlying reason is the deficient R&D in the pharma to produce novel quality drugs. It led to an increasing demand for high-value products such as biopharmaceuticals, complex generic drugs, and cell-based or gene therapy drugs through the required innovation that meets global standards.[16] The Policy emphasises the need to incentivise the private sector to invest to provide seamless regulatory frameworks and strengthen industry academic collaboration. India endorses the WHO's 'One Health' idea to adopt a unified animal and human health approach to avoid COVID-19-like pandemic.[16] The Policy also stressed the creation of white-collar jobs in the health and allied sectors in the coming decade.

Push and Pull Incentives

Numerous push and pull incentives have entered the domain of antimicrobial innovation. The former helps develop new antimicrobial products by mitigating financial risks, leveraging better prospects for the investors to invest, while the latter focuses on attracting investors to 'the antimicrobial development market through outcome-based rewards.'[17] The push incentives include "research funding, tax incentives and public private partnerships" while "market entry rewards, de-linkage models and patent buyouts" set the examples of pull incentives.[17]

Direct Grants for Antibiotic Innovation

It indicates the direct public funding to SMEs in innovative developed countries (e.g. "the United States Small Business Innovation Research Initiative (SBIR)" operated by the National Institutes of Health.). Though the funding focuses on the early stages of the drug development process, it could have a significant public health impact on such interventions. "The New Drugs for Bad Bugs programme (ND4BB)" under "the Innovative Medicines Initiative (IMI)" and "the Biomedical Advanced Research and Development Authority" (BARDA) grants of the US Department of Health and Human Services fall within this category.[4]

Public-Private Partnerships

Public-private partnerships in the biomedical sector has been more inclusive compared to the conventional PPP model, as the former includes additional players such as 'health foundations, patient organizations, and regulatory scientists.'[17] The State of Kerala in India sets an example of a government-supervised public-private partnership that affects the implementation strategies of public health.[18] 'Combating Antibiotic Resistant Bacteria

Biopharmaceutical Accelerator' (CARB-X) is a perfect example of public-private partnership that supports push incentives and provides funding and technical assistance to developers for defined projects targeting 'high priority medical needs from the pre-clinical research stage up to phase 1 clinical trial'.[19] The other prominent PPPs engaged in the R&D of antimicrobial products include Global Antibiotic Research and Development' (GARDP), European Union's 'Innovative Medicines Initiative' (IMI) and 'New Drugs for Bad Bugs' (ND4BB) programme.[17]

Milestone Prizes

These prizes are rewards for successfully completing a specified set of R&D objectives. They can be linked to "specific milestones in the R&D process or to a Target Product Profile of a desired end product."[4] Under this mechanism, payment is made on success only, and conditions, including patent buyout, could be imposed on the winner. The mechanism must be streamlined and equipped with good governance through governance institutions. However, the flip side of this mechanism, which runs on the "no-cure-no-pay" principle," is that it places much risk on the product-developing entity alone. This model does not incentivise cash-constrained companies.[4]

Patent Buyouts

Michael Kremer proposed the concept of patent buyout "inspired by the example of the patent for daguerreotype photography, which the French government purchased in 1839 and placed without charge in the public domain."[20] It led to the wider adoption of this early form of photography worldwide. Kremer proposed the idea of patent buyouts to the innovators with the option to sell their patent rights to the US government at 'prices equivalent to their estimated private value as determined at auction'.[6] The government then "make the innovation available to the public without charging any licensing fee".[6] The idea of patent buyout seems promising in areas such as antimicrobial drugs and other crucial health innovations that makes the new drugs available at a price nearly like the generic drugs and enhance the social value, it minimises the dependency of the innovation on the recoupment of the investment through "the monopoly prices in a fixed time frame". It may eliminate the possibility of winning "a high price in the current system typically branded drugs with few competitors", enhancing the social gains.[6]

However, patent buyout options are not without challenges as the auction "needs to be carefully structured to determine the correct price".[6] The price determined through auction may not be feasible for the antibiotic drugs, which may need some subsided price to promote innovation. Moreover, "the Government may misuse the purchasing power and force the sale of patents on confiscatory prices".[6] This may be coupled with the political challenges in making the reform in patent system. Nevertheless, the new challenges in the innovation process of health care and other fields led us to rethink over the new/alternative patent strategies as well as the structural reforms of patent system and therefore, the discussion about the patent buyouts in the current scenario makes sense.[6]

Pooling Funds

Pooled funds could be handy in addressing the global crises of developing new antibiotics, and it will also help delinking and decoupling efforts, replacing the reliance on 'unit-based revenue streams': "…[p]urchasing power needs to be pooled at one level to aggregate demand, at least at the health system or health insurer level. Pooled funding could both delink revenues from R&D costs and decouple revenues from volumes."[4]

Market Entry Award

Under this model, the awards are funded by an "antibiotic investment charge" that would be imposed widely on the pharmaceutical sector and applied on a "pay or play" basis.[10] By implication, "companies could either pay the charge or invest in R&D deemed useful for AMR". Market Entry Awards face criticism since many pharmaceutical companies may not be interested in AMR R&D and hence consider these awards another tax. Therefore, many suspect that it may not encourage R&D and innovation. Instead, they point out some other vital issues related to this award, e.g. how IP associated with this award would be handled: "would IP rights simply be transferred on receipt of the reward, or would there be a sliding scale with a limited sub-license at the other end of the compendium?"[10]

Patent Term Extension

One of the proposals allows "the developer of a new and high-value antibiotic to be rewarded with the opportunity to extend the patent term of another medicine to enable recuperation of R&D spent, given that the market for any new antibiotic will likely remain very small."[10] However, it also faces criticism from NGOs on the count "that the ultimate price of the extended "blockbuster" medicine would outweigh the cost of antibiotic R&D."[10]

Exchangeable Voucher

This model includes two sets of vouchers. One relates to transferable IP rights, while the other concerns "a priority review of any medicine approval by a regulator". As a result, a medicine could receive an accelerated review to place it on the market quickly. However, 'the limitation of this model is that its value would diminish if there was a significant increase in voucher availability.'[10]

International System of Governance

G20 Leaders' declaration called for a new international R&D Collaboration Hub – "to maximise the impact of existing and new antimicrobial basic and clinical research initiatives, and to further examine practical market incentive options."[10] Global Public-Private Partnership innovate through public-private partnership by relaxing IP protection to make it more accessible.[10] WIPO Re:Search Consortium is an excellent example of public-private partnership for accelerating "the discovery and product development of medicines, diagnostics and vaccines by providing solutions to the people affected by neglected tropical diseases, malaria and tuberculosis". The Consortium facilitates its aim "by making IP and know-how available to the global health research community". It exemplifies how IP-related issues could be better managed to support the development and maintenance of research partnerships. The research collaborations under this Consortium are based on "the guiding principles establishing essential parts of the prospective license agreements". It saves the efforts and costs of negotiating the licensing agreement.[10] WIPO Re:Search Consortium could be "a model for AMR/MDR research to proactively identify and facilitate collaborations that connect industry to academic and other non-profit researchers."[10] The experience gained from this consortium may be instrumental to Global Antibiotic Research and Development Partnership (GARDP) with its primary objective of fulfilling the R&D gaps in cases where commercial incentives are insufficient.[10]

Global Innovation Fund

A global innovation fund was proposed as another incentive model for innovation in AMR. This seems like a holistic approach yet is plagued with some real-world challenges, including coordination and collaboration and reaching an agreement to further common R&D priorities due to 'the diverse burden of AMR/MDR around the world'.[10] Since the developers of the new antibiotics could not ensure a similar reward to 'other areas of medicine, such as oncology or cardiovascular health', scholars emphasise 'the direct government involvement in the development of antibiotics'.[21] The TB Alliance sets a real-world example of public funding support to develop antibiotics: TB-Alliance, the maker of Pretomanid for drug-resistant tuberculosis, "is a not-for-profit product development partnership … between the public, private, academic, and philanthropic sectors to drive the development of new products for underserved markets".[21] Private industries too developed a large chunk of antibiotics recently approved, and even the TB Alliance has been primarily 'funded and comprised of members from the private sector'. Therefore, the drug developers play significant role in drug development, "they are best suited to develop medicines, just as inventors are best suited to invent".[21] Here, it is pertinent to inquire how society and states encourage innovators to invent new antibiotics.[21]

Access to New-Generation Antibiotics at the Global Level

At the international level, the accessibility to new-generation antibiotics should be need-based, and the need is to be assessed by an independent panel of technical experts in the same line as "the Green Light Committee Initiative that assesses country applications for access to second-line anti-tuberculosis medicines for effective treatment of MDR-TB".[21] Regarding the access to antimicrobial drugs in LMICs, Pfizer and Sanofi have established global not-for profit programmes "to expand access to antibiotics and antifungals ensuring sustainable access".[22]

Global Stewardship and Pharma Companies

To effectively address the menace of AMR, in addition to R&D and innovation initiatives, stewardship programmes must be integrated globally. Companies also need to contribute to the stewardship program as they "need to provide information on how much of their antibiotic manufacturing ends up in waste in the environment, how they are monitoring the supply compliances."[22] They need to invest in 'R&D for pathogens in the highest threat category'.[22]

In India, surveillance is the most important aspect of antimicrobial drugs as it helps identify the pathogens and suggests what kind of antibiotics they need. Indian Council of Medical Research (ICMR) is putting thrust on surveillance but India being a vast country need more district hospitals and community-based resistance to monitor, which seems a daunting task.[23] Global Action Plan introduced by the WHO stresses disseminating knowledge through surveillance and research. However, the global research on AMR is highly concentrated in the developed countries and developing countries including India and other countries in South Asia reflect a very little participation in the same. India launched a 'National Action Plan on AMR in 2017' to promote investment in research. However, research on AMR in India has been primarily focussed on epidemiology and research mechanism of AMR, followed by "the development of interventions to tackle AMR rather than research on new interventions and alternatives to antimicrobial treatment".[24] In India private companies dominate the patent filing in the antimicrobial sector followed by academic research organisations and individual inventors. Most of the patents are restricted to "new formulations and new antibiotic compounds from natural resources".[24] A recent report of WHO on AMR surveillance shows the lack of national surveillance data on resistant pathogens in India. Though the ICMR had launched the 'Antimicrobial Resistance Surveillance and Research Network' in India in 2013, the programme is limited to an inadequate number of labs. A robust framework of AMR Surveillance backed by a national sustained investment and incentive mechanism for disruptive innovations in antimicrobial sector through public-private partnership is pertinent.[24]

Alternatives to the Traditional Antibiotics

One of the limitations with the traditional antibiotics is that "the inherent properties of these small molecules being mostly broad spectrum and non-programmable".[25] However, with the scientific advances in the microbial studies, scientists develop new approaches to address antimicrobial resistance. One of the most prominent approaches is to develop next generation antibiotics, which may overcome the limits of traditional antibiotics. Several new antimicrobial agents include "bacteriophage-based therapy, CRISPR-Cas-based antimicrobials, and microbiome-derived antimicrobial agents".[25] Researchers suggest a multipronged approach to tackle AMR. The science journal Nature suggests five strategies that scientists are currently pursuing which comprises of tapping the natural products (e.g. microbe molecules with a narrower target range), recognising and utilising the potential of AI-led antimicrobial screening, using combination therapies (also finding new combinations), improving clinical treatment of infection (immune assistance), and developing and promoting efficient diagnostics.[26]

The advent of AI changes the process of drug discovery and development; however, it poses new challenges before the law to keep pace with technology and keeps the Patent Office busy issuing guidelines for AI-enhanced drug development.[27] One of the most contentious aspects of AI-led invention is the contribution of human or human intervention to the invention. The contribution of AI in making inventions does not establish that it automatically becomes unpatentable; it is fact-specific and open for inquiry as if there is a significant contribution of a natural person. The facts are to be assessed by the courts by setting standards, and in the meantime, innovator companies must ensure that the new drug development does not solely rely on AI. They can use it for supplemental purposes targeted to perform specific tasks.[28] Trade secrets can also be used to protect 'data pertaining to small molecules, algorithms, source codes, chemical processes, and nearly any other kind of valuable information to pharmaceutical companies.[28]

Conclusion

Innovation in the antimicrobial sector is a diverse and multifactorial phenomenon, distinctively demonstrating its unique character compared to other pharmaceutical products. Diverse approaches within the patent system, such as non-exclusive patent licensing with conditions for stewardships, patent pooling, patent pledges and open and collaborative agreements, can play a vital role in promoting R&D and innovation in the antimicrobial sector. 'No one size fits all' is a relevant phrase in the context of the innovation puzzle of the antimicrobial sector, as different kinds of push or pull approaches can find their value in a contextual setting backed by the regulation, governance and policy interventions. Pooled funds, direct grants, market entry awards, patent buyouts, and exchangeable vouchers give plenty of options with inherent limitations. However, combining them to apply in each situation requires a subjective inquiry. Delinking the R&D costs and decoupling revenues from volumes need government support, and public-private partnership at the international, national, regional and local levels can be instrumental in finding a sustainable solution to antimicrobial resistance and encouraging sustainable innovation in the antimicrobial sector. It may also help combine the One Health approach to the innovation process of the antimicrobials. Given the global nature of antimicrobial resistance, well-coordinated efforts of the governments, institutions/organisations, and global R&D and innovation entities are pertinent to address the innovation conundrum of the antimicrobial sector.

Acknowledgement

This paper is based on the 'Work in Progress' presented by the authorin the Sixth IP & Innovation Researchers of Asia (IPIRA) Conference 2024organised by the IPIRA Network in collaboration with Foreign Trade UniversityVietnam, WIPO Academy, WTO, Texas A&M University, USA, Nanyang Technical University, Japanand others (Venue, Foreign Trade University, Hanoi, Vietnam, 18-19 January 2024). The visit was supported by the University of Delhi.

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