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The Crossroad between Intellectual Property and Clinical Trials: Balancing Incentives for Innovation with Access to Healthcare

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Intellectual property (IP) is essential for encouraging innovation in the pharmaceutical business, particularly in clinical trials. However, IP can also limit access to healthcare by making drugs and treatments unaffordable for certain populations. The pharmaceutical industry relies heavily on intellectual property protections to incentivize innovation and support the development of new drugs. Moreover, clinical trials play an indispensable part in the medication development process, providing the evidence needed to support regulatory approval and marketing. The intersection of intellectual property and clinical trials raises important legal and ethical issues that need to be carefully considered. This article analyses the significance of intellectual property in the process of drug innovation, its impact on clinical trials, and the ways in which intellectual property might affect the accessibility and price of new treatments. This paper also explores the balance between incentivizing innovation through IP and ensuring access to healthcare, notably within the setting of clinical trials.

It examines the history of intellectual property laws in the pharmaceutical industry, how patents and exclusivity encourage innovation, and how these incentives affect healthcare access. The paper also discusses alternative models for incentivizing innovation, such as open-source drug development and prize-based systems. The article concludes that while intellectual property is vital to encourage innovation in the pharmaceutical business, it must be balanced with efforts to assure universal access to healthcare. We argue that policymakers and industry stakeholders must work together to develop policies and practices that promote innovation while ensuring that new drugs are accessible and affordable to all.

Keywords: Intellectual Property, Clinical Trials, Innovation, Access to Healthcare, Pharmaceutical Industry, Patents, Exclusivity, Open-Source Drug Development, Prize-Based Systems

The pharmaceutical sector is an integral part of the healthcare system, as it provides crucial medications to treat and prevent a wide variety of diseases.[1] Development of new drugs is a time-consuming and resource-intensive process that requires major investment.[2] The pharmaceutical industry relies heavily on intellectual property (*hereinafter referred to as* IP) laws, particularly patents and exclusivity, to incentivize novelty and recoup the costs associated with research and development.[3] Moreover, clinical trials play a crucial role in the process of drug development,[4] providing the evidence needed to support regulatory approval and marketing.[5]

Clinical trial development for novel medicines and therapies is an expensive and time-consuming procedure. However, the use of IP in the pharmaceutical industry has been criticized for limiting access to healthcare by making drugs and treatments unaffordable for certain populations. The intersection of intellectual property and clinical trials raises important legal and ethical issues that need to be carefully considered.[6]On the one hand, the pharmaceutical sector need protection of intellectual property in order to foster an environment that encourages and acknowledges innovative ideas. The contradiction between protecting intellectual property rights and increasing public health and access to new medications, on the other hand, must be expertly managed to ensure that everyone has access to the advantages of drug development.[7]This study investigates the significance of intellectual property in the drug development process, its impact on clinical trials, and its effect on the accessibility and affordability of novel drugs.

Historical Development of Intellectual Property Laws in the Pharmaceutical Sector

The use of IP to protect pharmaceutical innovations dates back to the mid-19th century.[8] In 1855, the United States passed its first patent law for pharmaceuticals,[9] granting inventors a 14-year monopoly on their inventions.[3] This law was modelled after the patent system in place for other industries, such as manufacturing and agriculture.

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The 20th century saw a significant expansion of IP laws in the pharmaceutical sector.[10] The United States passed the Kefauver-Harris Amendments[10] in 1962, which required pharmaceutical corporations to establish the safety and efficacy of their goods prior to marketing them. This led to an increase in the cost and duration of clinical trials, further emphasizing the need for IP protection to retrieve costs of related research and development.

The Hatch-Waxman Act of 1984[11] further expanded IP protections for pharmaceuticals. This law created a system of exclusivity for new drug applications, giving drug manufacturers five years of exclusivity for their new products.[12] It also created a system of patent extensions for drugs that had been in development for a long time, providing additional IP protection for pharmaceutical companies.[13]

Role of Intellectual Property in Drug Development

The development of new pharmaceuticals and treatments is a labour- and resource-intensive process that necessitates significant financial investment. Bringing a new drug to market often takes 10–15 years and costs billions of dollars.[14] This is mainly owing to the substantial expenditures connected with clinical trials, which are essential to show the drug's safety and effectiveness.[15]

The pharmaceutical industry relies heavily on intellectual property protections to incentivize innovation and support the development of new drugs. Intellectual property protections include patents, trademarks, and copyrights, which provide legal rights to the owners of the intellectual property.[7]Particularly important to the medication development process are patents, which grant the drug's inventor exclusive rights for a certain time, often twenty years from the filing date.[16]

Patents foster innovation by giving a legal monopoly on the drug[17], allowing the inventor to recoup the expenses of research and development and create a profit. Without patents, corporations would have no motivation to invest in medicine development, as competitors could simply duplicate the drug and sell it at a lower price, diminishing the earnings of the originator.

The Role of Patents and Exclusivity in Incentivizing Innovation

Innovation in drug development and clinical trials is critical for improving public health and saving lives. However, it is an expensive and risky process that requires significant investments[18] in research and development (R&D) and intellectual property (IP) protection. Patents and exclusivity play a crucial role in incentivizing innovation in the pharmaceutical industry by providing firms with temporary monopoly rights to commercialize their drugs and recoup their R&D investments.[19]

In order to prevent others from selling, using, creating or importing their ideas without their permission, inventors are given legal rights known as patents.[20] In the pharmaceutical industry, patents protect drug compounds, formulations, manufacturing processes, and methods of use. Patents provide pharmaceutical companies with a temporary monopoly on their drugs, giving them the exclusive right to exploit their commercial value. By enabling pharmaceutical businesses to recuperate their R&D costs and profit from their drugs, patents encourage innovation. Pharmaceutical businesses wouldn't have the same incentives to spend in R&D without patent protection since they couldn't realise the full potential of their medicines.[21] Patents also encourage pharmaceutical companies to develop drugs for rare and neglected diseases, as they can earn higher prices for these drugs due to the limited competition.

Exclusivity is another form of IP protection that provides pharmaceutical companies with additional market exclusivity beyond the patent term. Exclusivity is granted by the regulatory agencies such as the US Food and Drug Administration (FDA) for a specified period to incentivize drug development for unmet medical needs. Exclusivity applies to different categories, including orphan drug exclusivity, paediatric exclusivity, and new chemical entity exclusivity. Orphan drug exclusivity is granted to drugs developed for rare diseases affecting fewer than 200,000 patients in the US. Paediatric exclusivity is granted to drugs that have been studied in paediatric populations. New chemical entity exclusivity is granted to drugs that contain a new active moiety that has not been previously approved by the FDA.

Without market exclusivity, pharmaceutical companies may be disinclined to spend in research and development for unmet medical needs. Pharmaceutical companies may not develop treatments for rare diseases without orphan drug exclusivity because the patient pool may be too limited to produce significant profits. Exclusivity also encourages pharmaceutical companies to conduct

clinical trials to prove the safety and efficacy of their drugs, as FDA approval is required to obtain exclusivity.

The use of exclusivity and patents to encourage innovation in clinical trials and medical research has various advantageous consequences on the economy and society. First, patents and exclusivity stimulate pharmaceutical companies to invest in research and development, which leads to the discovery of novel drugs and treatments that enhance public health and quality of life. Second, patents and exclusivity drive competition among pharmaceutical companies, leading to lower prices and increased access to medicines for patients. Third, patents and exclusivity contribute to the growth of the pharmaceutical industry, creating jobs and stimulating economic growth. Finally, patents and exclusivity provide a source of revenue for pharmaceutical companies, which they can reinvest in R&D for future drug development.

However, the role of patents and exclusivity in drug development and clinical trials has also faced criticism. Some argue that the high prices of drugs protected by patents and exclusivity limit access to medicines for patients, particularly those in developing countries. Others argue that pharmaceutical companies abuse the patent system by extending their patents through minor changes to the drug formulation or by engaging in patent litigation to delay competition. Critics further assert that exclusivity may delay the introduction of generic drugs to the market, hence increasing the cost of pharmaceuticals.

To address these concerns, policymakers have implemented various measures to balance the benefits and drawbacks of patents and exclusivity. In public health emergencies, compulsory licencing schemes allow generic drug manufacturers to make and distribute copyrighted drugs without the patent owner's agreement. Others have implemented patent review processes to ensure that patents are only granted for genuinely novel and non-obvious inventions.

Additionally, policymakers have incentivized drug development for unmet medical needs through various regulatory schemes. The FDA's Priority Examination Voucher programme gives pharmaceutical companies vouchers to speed up FDA review of future medication applications for unmet medical needs. The voucher can also be sold to other companies for a profit, providing an additional source of revenue for pharmaceutical companies.

Impact of Intellectual Property on Clinical Trials

The protection of IP rights can have substantial implications for clinical trials.[22] One of the most significant issues is the lack of data sharing, which can limit the ability of researchers to build on previous work. The lack of access to clinical trial data can limit the ability of researchers to conduct meta-analyses or secondary analyses that could lead to new insights or new drug development opportunities.

Data sharing can also be complicated by IP concerns, as companies may be reluctant to share data that could be used by competitors to develop similar drugs.[23] In some cases, companies may also seek to control the publication of trial results, which can limit the ability of researchers to access and analyze the data.

The lack of data sharing can also have important ethical implications, as it can limit the ability of patients to make informed decisions about participating in clinical trials.[24] Patients who participate in clinical trials are often motivated by the desire to contribute to the advancement of medical knowledge and to potentially benefit from new treatments. However, if trial data is not made available, patients may not be fully aware of the risks and benefits of participating in a trial.

IP protections can also have an influence on the design of clinical trials. Companies may seek to design trials that maximize the chances of obtaining regulatory approval, even if this means that the trial design does not fully reflect the needs of patients.[25] For example, companies may conduct trials that exclude certain patient populations or that use surrogate endpoints that may not fully capture the clinical benefit of the drug.[26]

The use of surrogate endpoints is a particularly controversial issue, as it can result in the approval of drugs that may not provide significant clinical benefit. Surrogate endpoints are measures that are used to predict clinical benefit, such as changes in laboratory values or other biomarkers.[27] However, the use of surrogate endpoints does not always translate into real-world clinical benefit, and there have been cases where drugs have been approved based on surrogate endpoints, only to be later found to provide little or no clinical benefit.

The Influence of IP Rights on Healthcare Access

While patents and exclusivity are necessary to incentivize innovation in the pharmaceutical industry, they can also limit access to healthcare. The high cost of drugs and treatments protected by IP can make them unaffordable for many people, particularly those living in developing countries. This has led to calls for greater access to affordable healthcare, particularly for life-saving drugs such as antiretroviral therapies for HIV and cancer treatments.[28]

The high cost of drugs is due in part to the cost of research and development, which is often recouped through high prices for patented drugs.[29] In order to achieve a return on their investment, corporations that invest in the creation of new pharmaceuticals must charge high costs for these items. While this may be a necessary incentive for pharmaceutical companies to continue investing in research and development, it can also limit access to these drugs for people who cannot afford them.[30]

In addition to this, the high price of medicines that are IP-protected can result in inequalities in access to medical treatment.[31]For instance, because to the prohibitively expensive nature of certain medications, residents of poor countries may be unable to acquire life-saving treatments that are easily accessible in affluent nations. This can exacerbate existing health disparities, as people in developing countries may be more likely to suffer from diseases that are treatable with expensive drugs.[32]

The Impact of Intellectual Property on Accessibility and Affordability of New Drugs

The protection of intellectual property can also have important implications for the accessibility and affordability of new drugs.[33] Patents provide exclusive rights to the inventor of the drug, which can limit competition and result in high prices. In some cases, companies may engage in practices such as evergreening, which involves making minor modifications to an existing drug in order to extend the life of the patent.

The high cost of drugs can have significant implications for patients and healthcare systems.[34] Patients may be unable to afford the cost of new drugs, even if they could potentially benefit from them. Healthcare systems may be unable to bear the cost of expensive new drugs, particularly if they are used to treat large patient populations.[34]

In some cases, the high cost of drugs can result in the rationing of healthcare, where patients are denied access to treatments that they need. This can be particularly problematic for rare diseases, where there may be few treatment options available.

There have been a number of proposals for addressing the high cost of drugs.[35] One approach is to promote the development of generic drugs, which can be sold at lower prices once the patent on the original drug has expired. Another approach is to promote the use of bio-similars, which are similar to biologic drugs but are not identical.[36]

Challenges at the Intersection of IP and Clinical Trials

The intersection of IP and clinical trials raises many challenges, including issues related to access, transparency, and cost.

Access

One of the key challenges at the intersection of IP and clinical trials is access to these trials.[37] Clinical trials are required to demonstrate the safety and efficacy of new pharmaceuticals, and access to these studies is required to ensure that novel therapies are safe and effective. However, access to clinical trials is often restricted, with many trials being conducted in developed countries, where the cost of conducting trials is lower and the regulatory environment is more favorable.[25] This can limit access to new treatments for patients in developing countries, who may not have access to the same level of healthcare as those in developed countries.

Transparency

Another challenge at the intersection of IP and clinical trials is transparency. In order for the results of clinical trials to be trusted by healthcare providers and patients, they must be transparent and publicly available. However, the publication of clinical trial results can be delayed or withheld due to concerns about protecting proprietary information or negative results that could harm the reputation of a drug or company. This can have serious implications for patient safety, as negative results or safety concerns may not be fully disclosed, leading to potential harm to patients who may not have access to all of the available information.

Cost

The cost of clinical trials is also a significant challenge at the intersection of IP and clinical trials.

Clinical trials can be extremely expensive, with costs ranging from hundreds of millions to billions of dollars. The high cost of clinical trials is one of the factors that contributes to the high cost of drugs, as companies need to recoup their investment in R&D and clinical trials in order to remain profitable.[2] This can lead to high drug prices that may be unaffordable for some patients, particularly those in developing countries.

Initiatives to Address the Challenges

There have been a number of initiatives aimed at addressing the challenges at the intersection of IP and clinical trials, including initiatives related to access, transparency, and cost.

Access

One initiative aimed at increasing access to clinical trials is the establishment of clinical trial networks, which bring together researchers, healthcare providers, and patients to conduct clinical trials in developing countries.[38] These networks aim to improve access to clinical trials for patients in developing countries, while also providing researchers with access to a broader patient population.

Transparency

The introduction of public clinical trial registries, which oblige corporations to register their clinical trials and publish their results to a publicly available database, is among the initiatives designed to increase the transparency of clinical studies.A global movement called the International Clinical Studies Registry Platform (ICTRP) seeks to make sure that all clinical trials are registered and that the findings of those trials are made available to the public.[39]

Cost

Alternative trial designs, such as adaptive trials and master protocols, which allow numerous therapies to be evaluated concurrently and decrease the number of people needed for each study, are among the initiatives aimed at lowering the cost of clinical trials.[40] In addition, the use of real-world evidence, which involves using data collected from routine clinical practice, can also help to reduce the cost of clinical trials by providing a larger patient population at a lower cost.[41]

National Perspective

The National Intellectual Property Rights Policy of 2016[42] acknowledges India's existing legislative framework that is compliant with the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, which aims to protect intellectual property rights (IPRs). The policy also aims to address India's developmental concerns by utilising the flexibilities provided in the international regime, thereby achieving a balance between the two objectives. On May 12th, 2016, the Union Cabinet approved a policy with the aim of promoting awareness regarding intellectual property rights (IPRs) and emphasising their significance as a valuable financial asset and economic instrument.[43] The aforementioned policy acknowledges the significance of ingenuity and inventiveness in the advancement and expansion of a knowledge-based economy. The notion posits that innovation is synonymous with the creation of intellectual property. The policy has a dual objective of facilitating the commercialization of intellectual properties through the dissemination of knowledge and reducing administrative obstacles by streamlining procedures.

Impact of the Policy on Pharmaceutical and Information Technology Industry in India

India is globally recognised as a major contributor to the pharmaceutical industry, with a significant presence in the export market. It has earned the moniker of the 'Pharmacy of the World' due to its reputation for providing affordable life-saving drugs to developing countries. According to a report by Equity Master, the Indian pharmaceutical market ranks third in terms of volume and thirteenth in terms of value.[44] India holds the position of being the foremost supplier of generic drugs worldwide, with its generic drugs constituting 20% of global exports in volume.[45] The pharmaceutical industry in India is valued at approximately $4.5 billion and is experiencing an annual growth rate of 8–9%.[46] The robust growth in question can be attributed, in part, to the implementation of a rigorous intellectual property rights (IPR) framework as well as the pivotal role played by the Indian judiciary in addressing patent and licencing concerns and protecting the interests of IP proprietors.

The enhanced accessibility of generic drugs has facilitated the provision of quality pharmaceuticals at an affordable price point to a vast number of impoverished individuals globally. The policy recognises the significance of the generic drug industry, which has economic and social relevance. It recommends implementing robust measures to

combat the counterfeiting of generic drugs. The Indian pharmaceutical sector is a dominant player in the global market for generic drugs, accounting for more than half of the world's vaccine supply.

India has become a prominent hub for clinical trials, contract research, and manufacturing endeavours, primarily due to the expansion of the biotechnology industry. The demand for various high-value biotech products has led to the establishment of numerous foreign enterprises in India.

Innovation and IPRs

The Intellectual Property Rights (IPR) Policy operates under the premise that ideas safeguarded by IPRs are consistently transformed into commercialised products and services, thereby endowing IPs with monetary worth. Merely assigning intellectual property rights to novel concepts does not necessarily lead to the creation of new goods or services. If the potency of the Intellectual Property Rights (IPR) system was indeed crucial in fostering innovation, then India would have experienced a surge in inventive pharmaceuticals during the pre-1970 era, when the nation permitted product patents in the pharmaceutical industry. India had to wait until the enactment of the Patents Act of 1970, which permitted solely processing patents in the pharmaceutical industry with a reduced duration of protection, to facilitate the availability of contemporary life-saving medications within the nation. The emergence of a robust generic pharmaceutical industry in India was significantly influenced by the Patents Act of 1970. However, the innovation ecosystem that facilitated the development of pharmaceutical innovations in India was primarily fostered by the collaborative efforts of the government, the public sector pharmaceutical industry, and universities.

Indian Drugs and Pharmaceuticals Ltd. (IDPL) and Hindustan Antibiotics Ltd. (HAL),[47] both public sector pharmaceutical companies in India, have acquired medical technologies from foreign countries, international organisations such as the World Health Organisation (WHO), and foreign companies.[47] The government provided support and assistance in promoting the exchange of technological advancements between the aforementioned corporations. In instances where the technology collaboration agreements between the two firms and their foreign counterparts prohibited the transfer of technologies, the government resolved the issue by facilitating the transfer of technologists from one company to the other. The sharing of technology between Merck & Co. of the United States and HAL was met with objection when Merck & Co. expressed concern over the sharing of their streptomycin technology with IDPL. Additionally, the Soviet Union strongly opposed the application of Merck & Co.'s technology to IDPL. As a solution, the government appointed a senior technologist from HAL to work in IDPL's antibiotic plant. The technological advancements generated by these public-sector enterprises were not only disseminated among themselves but also diffused to the private sector through personnel mobility. The noteworthy role of public sector companies in the development of human capital and business development is a significant contribution. The stakeholders collaborated with universities to design a curriculum that offers tailored instruction to meet the specific training needs of the pharmaceutical industry. The establishment of demand was not limited to skilled labour but also encompassed specialised capital and other services, thereby facilitating the growth of upstream and downstream enterprises. The aforementioned dynamism was a driving force behind the establishment of a bulk drug manufacturing sector in Hyderabad, which included the synthetic drug plant operated by IDPL. The emergence of innovation is a result of the collaborative interaction among various entities, and the precise impact of the intellectual property rights framework on this process remains ambiguous.

Alternative Models for Incentivizing Innovation

While IP is an important tool for incentivizing innovation in the pharmaceutical industry, there are alternative models that may be better suited to promoting access to healthcare. Open-source drug development is one such model.[48] In an open-source drug development model, researchers and pharmaceutical companies collaborate to develop new drugs and treatments, sharing their knowledge and expertise.[49] This allows for a more collaborative approach to drug development, potentially leading to faster and more efficient development of new treatments.

Another alternative model is a prize-based system, in which companies are awarded a prize for developing a new drug or treatment that meets certain criteria.[50] This model is based on the idea that

companies are more likely to invest in research and development if they are guaranteed a financial reward for success, rather than relying on patents and exclusivity to recoup their costs.

Both of these models have potential benefits for promoting access to healthcare. The pharmaceutical sector may collaborate and innovate more as a result of open-source drug development, which could speed up and improve the creation of novel medications and treatments. A prize-based approach might offer businesses a more direct incentive to participate in research and development while simultaneously guaranteeing that the pharmaceuticals and treatments that are developed as a result are inexpensive and available.[51]

However, there are also challenges to implementing these alternative models. Open-source drug development may be challenging to implement in practice, as it requires significant coordination and collaboration between multiple stakeholders.[52] In addition, there may be concerns about the quality and safety of drugs developed in an open-source model, as there is no guarantee that these drugs will be subject to the same rigorous testing and regulatory requirements as those developed by pharmaceutical companies.

A prize-based system also has its challenges.[53] One of the potential drawbacks is that it might not offer businesses the motivation to put money into research and development. In addition, there may be challenges in determining the criteria for awarding prizes, as well as ensuring that the resulting drugs and treatments are accessible and affordable for those who need them.[53]

Striking a Balance between Incentives for Research and Access to Healthcare

There is no one solution that will solve all of the problems related to the need to strike a balance between access to affordable healthcare and incentives for innovation. However, by encouraging increased transparency and data sharing in clinical trials, as well as the use of adaptive clinical trial designs, we can ensure that patients have access to safe and effective medications while simultaneously driving innovation in the pharmaceutical business.

It is a difficult task to strike the correct balance between encouraging pharmaceutical sector innovation and advancing access to healthcare.[54] There is no universally applicable solution because the appropriate balance depends on a variety of factors, including the type of sickness being treated, the population affected by the disease, and the social, political, and economic environment in which the drug is manufactured and disseminated.

To achieve this balance, it is also important to ensure that the implementation of these solutions is responsible and ethical. This includes obtaining informed consent from patients, protecting patient privacy, and ensuring that patient safety is prioritized at all times.

Combining distinct models is one method for achieving a balance between innovation incentives and healthcare accessibility.[55] For example, a company could choose to patent a drug in developed countries, where there is a higher ability to pay, while making the drug available through a prize-based system in developing countries, where there is less ability to pay. This strategy would encourage the corporation to spend money on R&D while also guaranteeing that the drug is available and inexpensive for those who most need it.

Another approach is to use flexibilities in IP law to promote access to healthcare. For example, compulsory licensing allows governments to grant a license to a third party to manufacture a patented drug, without the permission of the patent holder.[32] This can be used to expand access to affordable drugs, especially in underdeveloped nations where the price of drugs can be a major barrier to healthcare.[56] However, the use of compulsory licencing is contentious since it may be interpreted as undercutting the motivation for businesses to engage in research and development.

Conclusion

The intersection of intellectual property and clinical trials raises important legal and ethical issues that need to be carefully considered. The pharmaceutical sector absolutely needs the protection of intellectual property in order to properly promote and reward innovation. At the same time, the tension that exists between safeguarding intellectual property rights and promoting public health and access to new pharmaceuticals needs to be carefully balanced so that everyone can reap the benefits of new drug research.

The pharmaceutical sector relies heavily on intellectual property to encourage innovation. Patents and exclusivity help companies recover R&D costs while fostering innovation and industry collaboration.

However, the high cost of drugs protected by IP can limit access to healthcare, particularly for people in developing countries. Alternative models for incentivizing innovation, such as open-source drug development and prize-based systems, have the potential to promote access to healthcare while also encouraging innovation. However, these models also have their challenges, and finding the appropriate balance between incentivizing innovation and promoting access to healthcare will require a nuanced and complex approach.

Policymakers and industry stakeholders must work together to develop policies and practices that promote innovation while ensuring that new drugs are accessible and affordable to all. This may involve greater transparency in clinical trial data sharing, a more patient-centered approach to clinical trial design, and a range of measures to promote the affordability of new drugs.

The ultimate objective should be to strike a balance between fostering innovation and ensuring that life-saving drugs and therapies are accessible and affordable to everyone who requires them. This will require collaboration between stakeholders, including pharmaceutical companies, governments, and patient advocacy groups, to develop innovative solutions that balance the needs of all parties involved.

The intersection between intellectual property with clinical trials is a difficult and crucial problem with major ramifications for the development of new medications and public health. By working together, policymakers and industry stakeholders can promote innovation while ensuring that the benefits of drug development.

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