Intellectual Property Rights: the Foundation for Sustained Investment in Biopharmaceutical Innovation

PhRMA Enterprise Report submitted for China Development Forum March 2023

Executive Summary

Robust protection and enforcement of intellectual property (IP) rights, including patents, regulatory test data and trade secrets, are critical to incentivizing investments in innovative industries such as the biopharmaceutical sector. Effective IP protection and enforcement provide the predictability and certainty necessary to support research and development (R&D) as well as delivery of new treatments and cures for patients around the world. Strong IP rights improve the business case for a company to conduct R&D and launch its innovative medicine in a particular market. For example, a recent statistical evaluation of over 50 markets indicates that those with regulatory data protection (RDP) have on average around three times as many innovative medicines available to patients compared to those without RDP and that more clinical trials are conducted in markets with RDP.[1]

China's leadership is highly committed to strengthening biopharmaceutical innovation and ensuring Chinese patients have greater access to innovative medicines. These objectives are an integral part of China's *14th Five-year Plan*, *Healthy China 2030* and a wide range of healthcare-related legislative and regulatory reforms. Throughout these reforms, China has made several improvements to IP protections for medicines and in developing a system that more closely aligns with international practices. It has established an early patent dispute resolution system, committed to establish patent term extension and adjustment and issued proposals on RDP. However, these reforms are not yet complete, and innovators still have much less certainty about the protection of their IP in China than they have in other markets that have fostered strong innovative biopharmaceutical industries.

We respectfully offer the following recommendations for China to strengthen its IP system to further encourage investment in biopharmaceutical innovation and enable greater patient access to lifesaving treatments and cures:

[1] See section I.C.

Patent Protection and Enforcement

Patentability—Unlike other major markets, China does not consistently accept data generated during the R&D process after a patent is filed, *i.e.*, data supplementation, resulting in denials of patents on new medicines in China that received patents in other jurisdictions. We recommend clear, consistent and coherent standards regarding acceptance of post-filing data for biopharmaceutical patents in China.

Patent Term Extension (PTE) and Patent Term Adjustment (PTA)—An effective pharmaceutical patent system includes mechanisms to adjust the term of a patent to compensate for patent office delays, *i.e.*, patent term adjustment or PTA, and to restore the patent term to compensate for a portion of the lengthy time required to develop and secure regulatory approval for pharmaceutical products, *i.e.*, patent term extension or PTE. We recommend that PTE and PTA be expeditiously effectuated in China.

Patent Enforcement—In order to foster a strong market for innovative and follow-on medicines in China, there should be an opportunity for patent disputes to be resolved prior to the marketing of any generic or biosimilar product. China has established an early dispute resolution mechanism in Article 76 of its *Revised Patent Law* and has issued several implementing rules and judicial interpretations. However, certain features of the system, such as the short approval stay for follow-on approval and unclear applicability to biologics, could make it difficult for China to achieve its intended goal of resolving patent disputes early to save resources and ensure continued patient access to medicines.

Regulatory Data Protection (RDP)

RDP provides protection for the comprehensive package of data that innovators must submit to regulatory authorities to demonstrate the safety and efficacy of a medicine for marketing approval. We recommend China adopt the highest international RDP standards, including 12 years for biologics and 10 years for small molecules, consistent with those in other countries that have robust innovative medicine markets.

Protection of Trade Secrets

Companies must have the ability to protect their confidential know-how (*e.g.*, manufacturing information) from disclosure and theft through trade secret

protection. This includes not only the ability to pursue remedies from private parties, but also through support from government agencies, to ensure that such information is only submitted when absolutely necessary and in a secure manner.

IP Sharing and Clinical Trials

China has globally unique requirements under the *Human Genetic Resources (HGR) Regulations* for IP sharing of discoveries during clinical research conducted in China and has proposed to link patentability with HGR requirements. We recommend reevaluation of these policies, which undercut a predictable IP environment for innovators, especially those considering simultaneous development in China.

In addition, we note that certain proposals for PTE and RDP would limit the availability or duration of such protections for drugs previously marketed outside of China, which is inconsistent with practices of major markets globally. Such an approach would also be contrary to China's innovation goals, making it more difficult for both foreign and domestic innovative manufacturers to benefit from the incentives that these protections offer for innovation, which may in turn impact decisions to develop and/or launch products in China at all. We recommend clarification that these biopharmaceutical IP protections would apply equally to all innovative products launched in China.

1. Introduction—IP Rights and Biopharmaceutical Innovation

China's leadership is keenly aware of the relationship between strong IP rights and innovation and has made important policy pronouncements in support of strengthened IP rights.[2] Such broad policy approaches are most effective when matched by coherent implementation throughout the relevant Chinese government agencies responsible for biopharmaceutical innovation through the drug development lifecycle.

1.1 Benefits of an R&D-Intensive Biopharmaceutical Industry

An R&D-intensive biopharmaceutical industry contributes to a market's economy through the creation of a large number of highly skilled, high-paying jobs. This industry's productivity is superior to the average of a market's economy. For instance, in the United States and Switzerland, markets with successful R&D-intensive biopharmaceutical industries, the productivity measured in total value added per full-time employee (FTE) is over 2.5 times, and 4 times higher than the total economy, respectively.[3]

Clinical trials also represent investments, both from domestic industry and that abroad. In addition to adding foreign direct investment and providing for more high productive research and development jobs, clinical trials help strengthen the healthcare system by improving the standard of care, improving infrastructure and ensuring continuous training of professionals, which enables access for patients to innovative therapies. Research has quantified the internal rate of return on investment in clinical research to lie between 39 and 64 percent.[4]

1.2 The Drug Development Lifecycle

Bringing innovative medicines to the market involves lengthy, risky and costly development processes. On average, it takes 10-15 years and USD 2.6 billion (RMB 17.7 billion) to develop one new medicine, including the cost of the many failures.[5]

Biopharmaceutical product development starts through basic research to understand

---

[2] *See, e.g., National Plan for Protection and Application of Intellectual Property Rights During the 14th Five-Year Plan Period (2021-2025)*; Ministry of Commerce (MOFCOM) and the Ministry of Science and Technology (MOST) *Measures Further Encouraging Foreign Investors to Establish Research Centers (2023)*.

[3] Copenhagen Economics based on PitchBook Venture Investment database (https://pitchbook.com/) May 2020; BAK Economics AG, The Importance of the Pharmaceutical Industry for Switzerland. Interpharma (2021); Ministry of Foreign Affairs, Denmark, The Danish Pharma and Biotech Industry (2021).

[4] Craig, J., Avila, A. C., Dale, V., Bloor, K., & Hex, N., Estimating the Economic Value of NIHR Biomedical Research Centres and Units, University of York (2021); Health Economics Research Group, Office of Health Economics, & RAND Europe, Medical Research: What's it worth? (2008).

[5] PhRMA, Research & Development Policy Framework, (https://phrma.org/policy-issues/Research-and-Development-Policy-Framework).

the relevant diseases and conditions and the ways in which medicines could target diseases in the body. Pre-clinical research on the therapeutic candidates may be conducted in laboratories and in animals to generate safety data and assess product characteristics prior to initiating clinical research.

The biopharmaceutical candidate may be tested in humans typically in different phases of clinical trials (traditionally there are three). Clinical research often begins with testing the basic safety of the biopharmaceutical product in a small number of healthy patients and culminates in large pivotal clinical trials that examine the drug's safety and effectiveness for specific indications in the intended population. There are many failures during this process; in the United States, for example, only 12 percent of the new molecular entities that enter clinical trials receive approval for marketing.[6]

At each stage of the development pathway, biopharmaceutical companies must make decisions about whether to invest in R&D, which markets to seek entry into and how best to structure complex arrangements with local entities and partners in order to make appropriate business decisions. Predictable IP systems are critical for biopharmaceutical companies to continue to make costly investments as product development moves forward.

1.3 The Relationship between Strong IP Rights and Innovation

Major markets around the world with highly innovative biopharmaceutical industries typically have strong IP protection and enforcement systems. In addition, empirical studies support the relationship between strong IP rights and innovation.

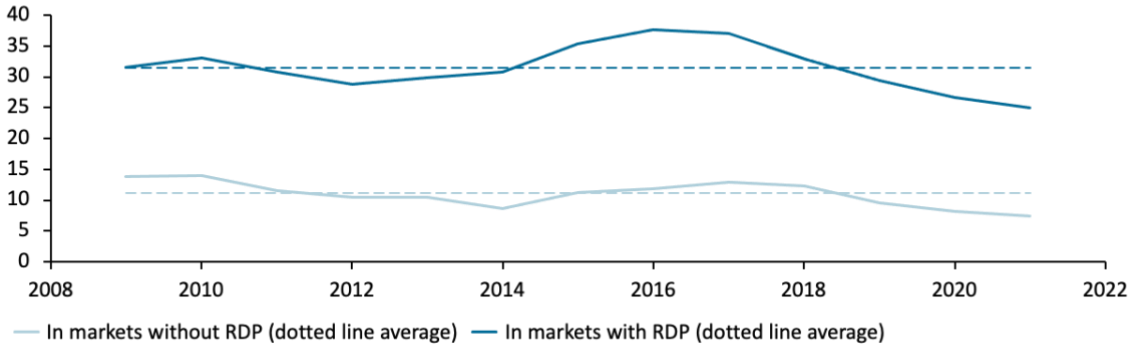
For example, recent statistical analyses across over 50 markets, where some have introduced RDP and others have not, provide strong evidence that RDP increases the availability of innovative medicines. Comparing the share of innovative medicines approved out of all innovative medicines launched globally in the last five years, markets with RDP have on average 31.5 percent of innovative medicines available in at least one market in the world (dark blue line in Figure 1), while markets without RDP have on average 11.1 percent of innovative medicines available (light blue line).[7] The difference means that patients in markets with RDP have around three times as many innovative medicines available as patients in markets without RDP.

[6] Id.

[7] Copenhagen Economics, Regulatory Data Protection for Pharmaceuticals: How adopting regulatory data protection will impact patients, industry, and Brazilian society (2023).

Figure 1. RDP and availability of innovative medicines

Percent of innovative medicines available[1]



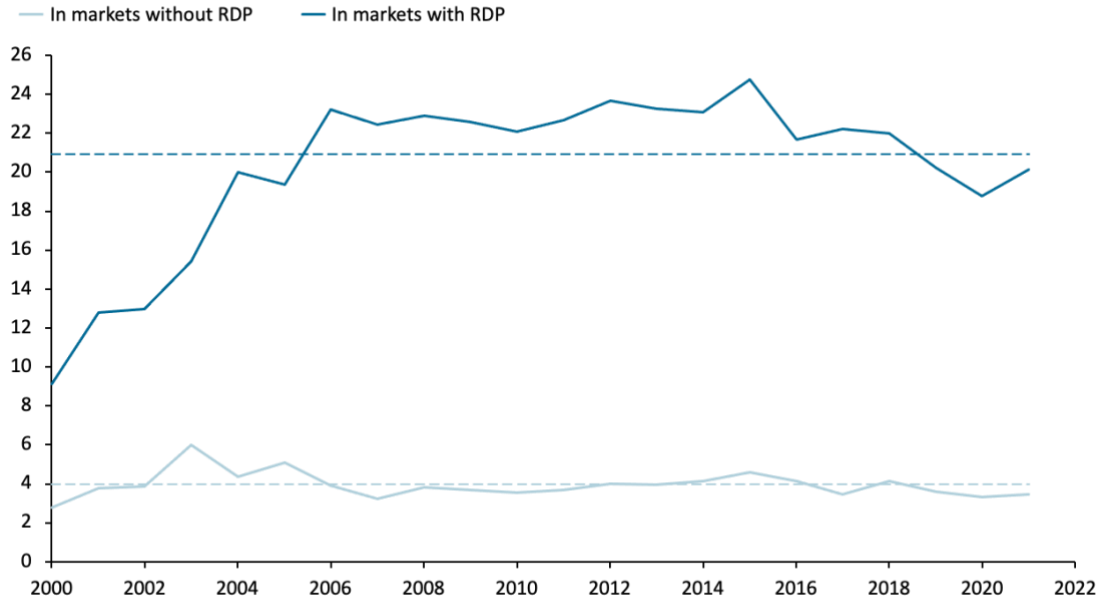
Note: 1) Based on 53 markets. Total averages are across markets and years.
Source: Copenhagen Economics based on data from IQVIA.

One of the reasons for this difference is that RDP, like other IP protections, improves the business case for a company to launch its innovative medicine. The business case is improved because the company would have better chances to enjoy a period of protection during which they may generate revenue to recoup the investment that went into developing and launching the innovative medicine (as well as the cost of those medicines that failed).

In addition, more clinical trials are conducted in markets with RDP. Comparing the average number of clinical trials conducted in markets with and without RDP, it was found that markets with RDP have on average 21 clinical trials per million capita, while markets without RDP have on average four. See Figure 2.[8]

[8] Id.

Figure 2. RDP and average number of clinical trials
Number of clinical trials per million capita[1]



Note: 1) Based on 54 markets. Total averages are across markets and years.
Source: Copenhagen Economics based on data from IQVIA.

2. Key Principles for Effective Protection and Enforcement of IP Rights

While there are differences across national systems, countries that offer effective IP protection and enforcement share certain common characteristics. This commonality reflects established international rules governing the protection of IP rights, which the vast majority of countries have agreed to follow. Specifically, the *World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)* sets out several basic principles regarding the protection and enforcement of IP rights.[9]

2.1 Clear and Predictable Rules that Support Innovation

The first key principle for the effective protection and enforcement of IP is the establishment of clear and predictable rules that lay out the IP protections available under a particular national system. These laws and regulations must be not only publicly accessible, but also clearly and consistently interpreted, and applied in a

[9] World Trade Organization (WTO) Website, "Overview: The TRIPS Agreement," (https://www.wto.org/).

predictable manner. Where rules are difficult to find, overly complicated or subject to arbitrary interpretation, predictability of the legal system is compromised and enforcement of IP protections is frustrated. Accordingly, the transparent and predictable application of IP rules is a fundamental building block for any effective IP enforcement system.

In addition, the rules themselves must provide sufficient protections for IP that support innovation. Even the most transparent and predictable system will fail if the protections it seeks to enforce are insufficient. In particular, IP protections must be sufficient to incentivize investment in innovative technologies and biopharmaceutical treatments. Many required minimum IP standards are provided in the *TRIPS Agreement* and other international trade agreements.

2.2 Fair and Efficient Resolution of Disputes

The second key principle for the implementation of effective IP enforcement is the establishment of mechanisms to provide for the efficient and fair resolution of disputes regarding IP rights. This requires a legal and administrative infrastructure that is capable of adjudicating claims relating to potential infringement of IP rights, that ensures IP rights holders have prompt access to legal or administrative procedures that are both "fair and equitable," and that provides the parties to the dispute an adequate opportunity to be heard.[10] Such procedures must not be unduly costly, complicated or time consuming.[11] Furthermore, consistent with the broader principles of transparency and procedural regularity, such proceedings should produce reasoned judicial decisions and/or administrative rulings that are provided to the public, or at a minimum to the parties involved in the proceeding.[12] Such decisions should also generally be subject to judicial review.[13]

2.3 Prompt Access to Effective Remedies

As a third key principle, national systems must also offer timely access to effective remedies that permit rights holders to prevent or deter infringement. This includes the ability to appeal or challenge the decisions of government agencies in a timely fashion and to enforce judgments against such government agencies. Of particular importance, rights holders must have access to judicial or administrative processes that allow them to seek remedies prior to incurring damages as a result of the alleged

[10] See *Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement*, Arts. 41(2)-(3).

[11] See *TRIPS Agreement*, Arts. 41(2).

[12] See *TRIPS Agreement*, Arts. 41(2)-(3).

[13] See *TRIPS Agreement*, Art. 32; Arts. 41(3)-(4); Art. 62(5).

infringement.[14]

3. Patent Protection and Enforcement

In order to support and promote innovation, countries should adopt systems that allow biopharmaceutical innovators to secure and effectively enforce patents. The following provides recommendations that China can implement to ensure effective patent protection and enforcement.

3.1 Patentability

To bring valuable new medicines to patients, biopharmaceutical innovators must be able to secure patents on all inventions that are new, involve an inventive step and are capable of industrial application.[15] China has established patent protection for medicines, their active ingredients, formulations and methods of use (*i.e.*, indications). However, "specific therapeutic methods" cannot be protected by patents in China. New specific therapeutic methods are new methods of treatment of a known indication with a known product (such as new dosage regimens, treatment of new subgroups of patients or new routes of administration). They are distinguished from new product forms (such as dosage forms and formulations), manufacturing processes and treatment of new indications, which can be protected by patents in China either directly or through use of the Swiss-type claim format. Most countries with strong IP laws provide patent protection for specific therapeutic methods either directly (by permitting methods of treatment to be patented) or indirectly (by permitting alternative claim formats, *e.g.*, Swiss-type claims). Incentives to develop such new specific therapeutic methods should be provided by the patent system because such new uses of existing medicines can bring important patient benefits, including methods of treatment specific to the Chinese population that may not be developed in the absence of a local incentive to do so. We recommend that the China National Intellectual Property Administration (CNIPA) revisit this gap in China's patent system and conform China's practice to that of many other countries.

Furthermore, it is important that patent examiners permit pharmaceutical companies to supplement data underlying their original applications to help demonstrate that the claimed invention, as supported by the originally filed disclosure, meets all the requirements for patentability. While we recognize that the CNIPA draft *Revised Patent Examination Guidelines (Revised Guidelines)* and judicial interpretations clarify the ability to consider post-filing experimental data,

[14] These international best practices are reflected in the provisions of U.S. international trade agreements. See *United States-Mexico-Canada Agreement (USMCA)*, Art. 20.51.

[15] See generally, *TRIPS Agreement*, Art. 27.1.

they have not been implemented in practice. We recommend establishing clear, consistent and coherent standards regarding acceptance of post-filing data in China for biopharmaceutical patents that reflect the realities of the drug development lifecycle. For example, unlike patent offices in the United States, Europe, Japan, Korea and other major markets, CNIPA does not consistently accept data submitted after a patent is filed to satisfy sufficiency and inventive step requirements, pursuant to Articles 26.3 and 22.3 of China's *Revised Patent Law*, respectively. This practice has caused uncertainty around the ability to obtain and maintain biopharmaceutical patents in China and has caused denials of patents on new medicines in China that received patents in other jurisdictions.

3.2 Patent Term Extension and Adjustment

An effective biopharmaceutical patent system should also accommodate special circumstances related to medicine development. This includes mechanisms to adjust the term of a patent to compensate for patent office delays, *i.e.*, PTA, and to restore the patent term to compensate for a portion of the lengthy time required to develop and secure regulatory approval for pharmaceutical products, *i.e.*, PTE.

China has incorporated PTA and PTE into its *Revised Patent Law* and the draft *Patent Law Implementing Regulations (PLIR)*, and the 2021 CNIPA draft *Revised Guidelines* and subsequent draft revision in October 2022 include language to provide both PTA and PTE. However, to date, these provisions have not been finalized. In addition, there remains significant ambiguity related to the scope of patents eligible for adjustment and extension, as well as the scope of protection provided. We recommend that CNIPA expeditiously finalize the draft *PLIR* and *Revised Guidelines* to address these ambiguities and provide clear direction as to how PTA and PTE will be determined. Without the final rules, it is impossible for patent holders to determine with certainty which patents are eligible for PTE, and as time passes, certain products may become ineligible for the protection as the remaining patent life of applicable patents diminishes.[16]

Furthermore, it is critical that these IP protections apply to medicines that are new to China. An application of a "new-to-the world" standard would deny PTE to innovative medicines first approved outside of China and lower the incentives for such products to be launched in China.

3.3 Patent Enforcement

Effective patent enforcement systems provide legal and/or regulatory mechanisms

[16] Pursuant to CNIPA *Interim Measures for the Implementation of the Relevant Examination Business Handling of the Revised Patent Law* (2023) Art. 6, patent owners must file PTE applications within three months of new drug approval to qualify for this protection.

to prevent the marketing of patent infringing products, such as generic and biosimilar follow-on products, during the term of the patent for the original innovative medicine. This principle is consistent with Article 28.1 of the *TRIPS Agreement*, which requires that patent holders have the right to prevent third parties from selling or offering for sale the patented product without the patent holder's consent.

Key elements of an effective biopharmaceutical early patent dispute system include that: (1) patentees are provided notice that a potentially patent infringing product may enter the market;[17] (2) patentees are provided adequate time and opportunity to take remedial action; and (3) the system provides procedures that allow for the resolution of patent disputes before a potentially patent-infringing product is launched on the market.

China established a biopharmaceutical early dispute resolution system in 2021 pursuant to Article 76 of its *Revised Patent Law*. This provision and its implementing measures[18] allow for much greater clarity on the three aspects of an effective patent enforcement system with regard to potentially infringing follow-on products. However, there are a number of ways in which this system can be improved. A survey of PhRMA member companies conducted in July 2022 evaluated companies' experiences with the newly established system and identified a number of issues and recommendations on how the system could be enhanced for better predictability and efficiency:

> *Ambiguities in scope of patent listability*—Several respondents noted that they were unable to register patents in China that are eligible for listing in the U.S. Food and Drug Administration's Orange Book or Purple Book. Furthermore, it appears that patents not registered may not be eligible for enforcement through the Article 76 mechanism. Conversely, in other markets that have implemented patent linkage systems, a broader set of patents can be registered and innovators can initiate patent disputes for both listed and non-listed patents as part of the patent linkage mechanism. There should be clear guidelines as to what patents can be listed for both chemical drugs and biological products, including the scope of patents covering active ingredients, as well as a medicine's formula, composition and uses. For example, the active ingredient should include patents that claim that ingredient by name, characteristics or structure, and the composition patent

[17] See *USMCA*, Art. 20.51.

[18] Specifically, the *National Medical Products Administration-CNIPA Implementation Measures on Early Resolution Mechanisms for Drug Patent Disputes (2021)* and the *Supreme People's Court Judicial Interpretation Regarding Patent Disputes Related to Pharmaceutical Registration Application and Registration (2021)*.

category should include medical devices that help introduce the medicine into the patient's body.

Deficiencies in notice to the marketing authorization holder (MAH)/patentee—According to the survey, more than 30 percent of respondents indicated that a notification was not provided by the generic applicant within 10 business days following acceptance by the National Medical Products Administration (NMPA) of the generic drug application. In addition, almost two-thirds of respondents reported receiving inaccurate or erroneous patent statements from generic applicants.[19] Such errors deprive innovators of the ability to initiate Article 76 proceedings. We recommend that NMPA establish guidance and procedures for correcting generic/biosimilar applicants' patent statements and clarify which patent statements enable an originator to initiate an Article 76 dispute.

Ambiguities in jurisdiction over patent disputes—Respondents who have initiated Article 76 disputes showed a strong preference for initiating the dispute in the courts versus at CNIPA. This has led to instances where the Article 76 proceeding is occurring in tandem with an invalidation proceeding regarding the same patents at CNIPA. This underscores the lack of clarity as to the nature of an Article 76 proceeding as compared to the pre-existing invalidity and infringement proceedings. Parallel proceedings before the courts and CNIPA may result in inconsistent decisions.

Insufficient time to initiate an Article 76 dispute—Respondents also indicated that the amount time to assess and initiate an Article 76 dispute was too short for the MAH or patent holder to coordinate with the follow-on applicant and secure the necessary information to assess whether to initiate an action and to then prepare, legalize and send the necessary documents to commence an Article 76 dispute in the courts. We recommend the time to initiate an Article 76 proceeding be extended from 45 to 75 days.

Insufficient stay period—Respondents expressed concerns that the 9-month stay is insufficient to resolve Article 76 disputes and a lack of clarity regarding how NMPA will ensure that biosimilars are not approved before parties have had a chance to resolve patent disputes. We recommend that the administrative stay of approval should be extended to 24 months, as

[19] Errors included receiving: Type 1 statements even though patents were registered (*e.g.*, because the generic applicant was seeking approval for a different dosage form); Type 2 statements even though the listed patents were unexpired and valid; and Type 4.2 statements for patents listed on other products.

proposed by NMPA in 2017,[20] and apply to patent disputes involving both small molecule medicines and biologics. A stay of 24 months reflects a more realistic timeline to resolve a patent dispute, particularly when foreign parties are involved, and is more consistent with global best practices. This does not mean that every Article 76 dispute would result in a 24-month stay; the adjudicating body could resolve the dispute faster and, once a final, non-appealable decision is reached, the stay would dissolve.

4. Regulatory Data Protection

In addition to ensuring sufficient protection and enforcement of patents, national systems should provide for adequate protection and enforcement of RDP. Distinct from patents, RDP provides a period of exclusivity for clinical data generated to demonstrate the safety and efficacy of biopharmaceutical products for marketing approval. In many cases, RDP may complement patents on innovative medicines, while in other situations RDP may be the only protection available. Strong enforcement of RDP is therefore critical for fostering research and development of new medicines and for advancing efforts to stimulate local and global biopharmaceutical innovation (see Section I.C).

RDP is particularly important for large molecule drugs (i.e., biological products). Produced using material from living organisms, biologics are complex and challenging to manufacture and may not be protected adequately by patents alone. Unlike generic versions of traditional chemical compounds, biosimilars are not identical to the original innovative medicine, which can lead to greater uncertainty about whether an innovator's patent right will cover a biosimilar version. Without the certainty of some substantial period of market exclusivity, innovators will not have the incentives needed to conduct the expensive, risky and time-consuming work to discover and bring new biologics to market.

China has made prior commitments to offer RDP, including in its accession to the WTO, its signature of the *TRIPS Agreement* and in the *China-Switzerland Free Trade Agreement*. The *TRIPS Agreement* has long provided that signatories must protect the test and other data submitted to regulatory authorities to secure approval of new medicines against both unfair commercial use and disclosure. Despite proposals to implement RDP in China both in 2018[21] and in 2022,[22] RDP still is not provided in China. To increase confidence and predictability for the biopharmaceutical industry, we recommend that China move quickly to provide

[20] NMPA, *Policies Regarding the Promotion and Protection of Innovators' Rights in Drugs and Medical Devices* (draft for public comments) (2017).
[21] *NMPA Measures on the Implementation of Drug Clinical Trial Data Protection* (draft for public comments) (2018).
[22] *Revised Implementing Regulations for the Drug Administration Law* (draft for public comments) (2022).

RDP at levels consistent with international best practices.

As previously noted, prior proposals for RDP would have limited the availability or duration of RDP for drugs previously marketed outside of China, a practice inconsistent with that of major markets globally. Such an approach would also be contrary to China's innovation goals, making it more difficult for both foreign and domestic innovative manufacturers to benefit from the incentives that RDP offers for innovation, which may in turn impact decisions to develop and/or launch products in China at all. Given the problems associated with a "new-to-the world" approach, we urge clarification that RDP would apply equally to all innovative products launched in China.

Consistent with Article 39.3 of the *TRIPS Agreement*, China has committed to (1) ensure that the test and other data (regulatory data) submitted by the innovator is not disclosed, and (2) to protect such data from unfair commercial use, *e.g.*, reference or reliance on the regulatory data without the innovator's authorization for a defined RDP term. As China seeks to further strengthen the innovation environment for biopharmaceuticals, we recommend that China adopt the highest international RDP standards, including:

1. RDP for small molecules and biologics that are new to China with a term of protection of 10 years for small molecule drugs and 12 years for biologics, consistent with the highest international standards;[23]

2. RDP for improved drugs of three years, consistent with markets such as the United States and Switzerland, for a change to a previously approved active ingredient in a small molecule drug, provided there is new clinical data from the applicant; and

3. RDP terms that are measured from the date of approval of a marketing authorization by NMPA.

5. Protection of Trade Secrets

Companies must have the ability to protect their confidential know-how (*e.g.*, manufacturing information) from disclosure and theft through trade secret protection. This includes not only the ability to pursue remedies from private parties, but also through support from government agencies to ensure that such information

[23] For example, the United States grants five years of RDP for small molecule drugs that contain new active moieties and 12 years of RDP for biologics, with both periods starting on the date of first approval in the United States. 21 U.S.C. § 355; 42 U.S.C. § 262. The European Union grants small molecule drugs and biologics ten years of RDP from the date of first authorization in Europe, with the possibility of an additional year based on approval of an additional indication.

is only submitted when absolutely necessary and in a secure manner.

China has proposed and adopted stronger trade secret protection laws and further harmonized its development requirements with those of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). However, China's requirements remain inconsistent with international standards in certain respects. For example, unlike other regulators, NMPA requires executed manufacturing batch records at the clinical trial application stage. This means that applicants must transport and submit this confidential information—essentially a recipe for the medicine—at a sensitive time, potentially risking disclosure. As this information is unnecessary for the review of other aspects of the clinical trial application, applicants should be allowed to provide it, if needed, during an inspection for marketing authorization.

Trade secret protections should also be strengthened in both the regulatory submission and IP dispute phases. Applicants should be permitted to redact sensitive information that is not necessary for the specific administrative process and to work with NMPA to submit information using secure methods, such as through encryption.

6. IP Sharing and Clinical Trials

China has globally unique requirements under the *HGR Regulations* for IP sharing for certain discoveries during clinical research conducted in China and has proposed to link patentability to the HGR data requirements. According to the *HGR Regulations*, any research conducted by foreign companies using Chinese human biological samples must be undertaken in collaboration with Chinese partners (*e.g.*, Chinese hospitals) and their "international collaboration" approved by the Human Genetic Resource Administrative Office (HGRAO). The *HGR Regulations* require that (1) the foreign and Chinese party jointly submit and own any patent applications in China arising from the results of any exploratory research; and (2) the two parties agree on an arrangement for rights to other IP (*e.g.*, know-how or data) or, in the event that there is no arrangement, jointly share the rights and benefits to this IP, including obtaining the consent of the other party to transfer those rights and sharing benefits according to their respective contributions. In practice, these rules mean that the HGRAO requires the parties to agree to jointly own the patents to the results of exploratory research and in several cases also the underlying data.

While not necessarily impacting rights over the investigational product, applicants are required to submit their clinical trial agreements (including the IP-related provisions) and insert or summarize those IP provisions in the application to HGRAO for international collaboration approval. This can result in multiple

revisions and resubmission to HGRAO that create delays to initiate a clinical trial and uncertainty as to the rights over certain aspects of pre-market research (*e.g.*, exploratory endpoints) and postmarketing studies. The CNIPA *Revised Guidelines* also include concerning provisions that may limit the ability for companies to patent inventions if CNIPA determines that the applicant has not complied with HGR requirements.

The IP sharing requirement and the HGR application process together form a significant hurdle and create uncertainty for foreign companies conducting clinical research in China. The requirements undercut a predictable IP environment for innovators, especially those considering simultaneous development in China, and should be removed to ensure that any transfer of technology as part of securing marketing approval for innovative medicines occurs on voluntary, market-based terms.

Conclusion

Strong IP protection and enforcement—covering patents, regulatory test data and trade secrets—provide a powerful incentive for investments in innovative industries, including the biopharmaceutical sector. PhRMA stands ready to share the experience of the multinational industry in markets around the world to support the continuous strengthening of biopharmaceutical IP rights in China and greater patient access to lifesaving innovative medicines.