

Biopharmaceutical R&D Requires Meaningful Patent Protection

- **Average cost to discover and develop a new drug is over a billion dollars with an average length of time around 12 years**
- **New active ingredients are protected by “compound patents” that are filed early in the development process & prior to any public disclosure**
- **Single patent specification is filed worldwide adhering to global standards for disclosure at the time of filing**
- **Patents cover generic structures and specific exemplified compounds**
- **Innovators often do not know which specific compound will be advanced for development until significantly after patent filing**

Current Application of Article 26.3 Is Inconsistent With Global Disclosure Standards

- **While Article 26.3 text is similar to US/EU disclosure requirements, SIPO Guidelines are being interpreted to strictly require data in the application as filed for each compound**
- **Newer Article 26.3 examination guidelines are being applied to patent applications filed years earlier under different guidelines**
- **Innovators are unable to supplement data during prosecution both in response to Article 26.3 and other rejections**
- **Even if patent is granted by SIPO, it will likely face a revocation proceeding before the PRB-often brought by a NPE**
- **Result is that key Chinese patents are not granted or revoked while corresponding patents in other IP5 countries are granted and upheld**

Recommended Next Steps

- **All applications, both pending and granted, should be treated consistently, applying global disclosure standards consistent with the other IP5 offices**
 - **If the specification teaches how to make and use the invention, it will generally be allowed, assuming substantive patentability requirements are met**
 - **Any concerns an examiner has about the properties of the compounds can be addressed by submission of data during examination**
- **Innovator biopharmaceutical companies would like to continue to engage with SIPO on this issue in a manner that supports the interests of China and the rest of the world**