REGULATORY DATA PROTECTION FOR BIOLOGICS UNDER THE ART.39.3 OF THE TRIPS AGREEMENT? AN ISSUE TO BE CONSIDERED BY CHINA

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Abstract:
As the global biologics market burgeons, the adequacy of international intellectual property protection frameworks under evolving pharmaceutical landscapes warrants scrutiny. This article examines whether Article 39.3 of the TRIPS Agreement mandates biologics regulatory data protection and analyzes this question under PRC laws. A meticulous analysis of pharmaceutical classification and Article 39.3 drafting history under the treaty interpretation principles demonstrates that Article 39.3 exclusively applies to new chemical entity drugs. China's Article 39.3 equivalent has mirrored the same position since China's accession to the WTO in 2001, despite its recent failed attempts to extend the protection scope to biologics. The article advocates establishing a biologics-specific regulatory data protection regime under the PRC laws. In light of biologics' structural complexity, the challenges of patentability, and reference biologics' vulnerability to biosimilar circumvention, patent law alone proves inadequate for innovation incentives. Empirical evidence from the U.S. and China highlights the role of regulatory data protection and market exclusivity in driving R&D investment and biotechnological breakthroughs. Addressing affordability concerns, this article, based on the latest Finnish empirical study, highlights that drug price reductions depend more on biosimilar interchangeability and reimbursement policies than mere market competition between reference biologics and biosimilars. Furthermore, aligning with international practices, including obligations under the China-Switzerland FTA, would fortify China's biopharmaceutical sector and global trade integration. In conclusion, while the TRIPS Agreement does not mandate biologics data protection, China's technological ambitions and public health objectives necessitate a sui generis biologics regulatory data protection regime balancing innovation incentive with equitable access, positioning China as a leader in the biotechnology era.
Key words: *Article 39.3 of TRIPS Agreement, Treaty Interpretation, Regulatory Data Protection, Biologics and Biotechnology, Pharmaceutical Patent and Data Exclusivity*

I. INTRODUCTION

The year 2025 marks the 30th anniversary of the entry into force of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). Commentators have long marveled at the TRIPS Agreement's success in establishing international minimum standards for the protection and enforcement of intellectual property rights,[1] and undoubtedly, the TRIPS Agreement made indelible contributions to international intellectual property protection and promoted technological developments all around the world.[2]

However, as Bob Dylan wrote in his famous song *The Times They Are a-Changin'*, the wheel of technology has spun fast, pharmaceutical technology in particular, advancing by leaps and bounds compared to thirty years ago: in 1995, the Human Genome Project - the theoretical foundation for modern biological products – had just completed the first physical map of the human genome. The completion of the Human Genome Project in April 2004 heralded the era of modern biologics represented by antibodies, chimeric antigen receptor T-cell (CAR T-cell) and mRNA technology etc., catalyzing a paradigm shift in the pharmaceutical development and profoundly transforming the healthcare and pharmaceutical industries.[3] By the year 2023, the global biologics market had already reached US$ 480.00 billion, accounting around 33.01% of the global pharmaceuticals market, and is estimated to reach US$ 752.1 billion (45.43% of global pharmaceuticals market) by fall 2028.[4] Biosimilars, which are highly similar to the approved reference biological products, have also positioned themselves at the epicenter of this biologics innovation wave: in more than two decades following the TRIPS Agreement went into effect, no biosimilars had ever been approved in the United States (U.S.), Canada, Australia, Japan, or the European Union (EU). However, between 2011 and 2022, 59 follow-on biologics products were approved as biosimilars in the jurisdictions above.[5]

Given that access to biologics test data is essential for bringing

1 Peter K. Yu, *Data Exclusivities and the Limits to TRIPS Harmonization*, 46(3) FLA. STATE. U. L. REV. 641, 641 (2019).

2 *See generally* Ryan Cardwell & Pascal L. Ghazalian, *The Effects of the TRIPS Agreement on International Protection of Intellectual Property Rights*, 26(1) INT'L TRADE J. 19 (2012); Giuseppe Di Vita, *The TRIPS Agreement and Technological Innovation*, 35(6) J. POL'Y MODELING 964 (2013).

3 Peter K. Yu, *Data Exclusivity in the Age of Big Data, Biologics and Plurilaterals*, 6(1) TEX. A&M L. REV. ARGUENDO 22, 22 (2019).

4 FROST & SULLIVAN, INDEPENDENT MARKET ASSESSMENT OF THE GLOBAL AND INDIAN CRDMO MARKET 4 (2024), https://sailife.com/files/investors/frost-sullivan-industry-report.pdf.

5 *See* Kevin Klein et al., *The Global Landscape of Manufacturers of Follow-on Biologics: An Overview of Five Major Biosimilar Markets and 15 Countries*, 37(2) BIODRUGS 235, 240 (2023).

biosimilars to market,[6] leading pharmaceutical companies with numbers of biologics pipelines and industry stakeholders have become increasingly concerned about the protection of biologics test data (hereinafter referred to as "biologics regulatory data"[7]), in addition to biologics patent protection.[8] As a result, in recent years, the protection of biologics regulatory data has become a focal point in international intellectual property rights protection negotiations.[9]

Although Article 39.3 of the TRIPS Agreement (Art.39.3) provides minimum standards for the regulatory data protection of certain pharmaceuticals, ambiguities persist with respect to its applicability to biologics, and academic and practical opinions on the matter continue to diverge.[10] Turning to China, the world's second-largest pharmaceutical market in the world – concerns over biologics regulatory data protection has also been raised.[11]

This article aims to examine and discuss two outstanding issues regarding biologics regulatory data protection: (1) Are TRIPS Agreement Member States obligated to protect the biologics regulatory data under Art.39.3? and (2) Does China, since it transformed Art.39.3 into its domestic law in 2002, protect biologics regulatory data under the PRC laws? If not, should China protect it? Section II will explain what regulatory data of pharmaceuticals is and why it is important in the pharmaceutical industry. Section III will rely on the TRIPS Agreement negotiation materials to introduce the background of Art.39.3 drafting for a better understanding of the

6 *See* discussion *infra* Section II.0.

7 The concepts of "test data", "biologics regulatory data" and "undisclosed data" will be discussed in detail; *see* discussion *infra* Section II.0.

8 *See generally GSK Public policy positions: Regulatory Data Protection*, GLAXOSMITHKLINE (Apr. 2014), https://ca.gsk.com/media/2957/regulatory-data-protection-policy.pdf; *Global Intellectual Property Rights*, Pfizer (May 2020), https://cdn.pfizer.com/pfizercom/Global-Intellectual-Property-Rights-Final-May2020.pdf; *Novartis Position on Regulatory Data Protection*, NOVARTIS (Dec. 2023), https://www.novartis.com/sites/novartis_com/files/regulatory-data-protection.pdf;*Public Policy Statement: Intellectual Property*, MSD (Feb. 2024), https://www.msd.com/wp-content/uploads/sites/9/2025/04/IntellectualProperty_MSD_FEB2024.pdf; *Merck Position Statement: Intellectual Property Rights*, MERCK KGAA (Feb. 2025), https://www.merckgroup.com/company/who-we-are/en/healthcare/Intellectual_Property_Rights.pdf.

9 Yu, *supra* note 1, at 676 ("[A]rticle 18.51 of TPP, which covers biologics, was among the most controversial provisions toward the end of the TPP negotiations.").

10 *See* discussion *infra* Section III.0.

11 *See generally* Tongxin Qian (钱童心), *Quan'guo Zhengxie Weiyuan: Jianyi Dui Shengwuyao Shiyan Shuju Sheli Shinian Yishang Baohuqi* (全国政协委员朱同玉：建议对生物药试验数据设立十年以上保护期) [*Tongyu Zhu, Member of the Nat'l Comm. of Chinese People's Pol. Consultative Conf.: Recommendation to Establish a Protection Period of More Than Ten Years for Biologics Regulatory Data*], DIYI CAIJING (第一财经) [YICAI] (Mar. 4, 2024), https://www.yicai.com/news/102013336.html.

undisclosed test data regime and properly interpret Art.39.3, therefore answering the first question "Are TRIPS Agreement Member States obligated to protect biologics regulatory data Art.39.3?" Section IV will discuss the status quo of biologics regulatory data protection in China.[12] Section V, following the conclusion in Section IV, will provide different justifications to argue why the biologics regulatory data should be protected in China from the *lex ferenda* perspective. Section VI will present the overall conclusion of this article.

II. REGULATORY DATA AND ITS IMPORTANCE

A. What is the regulatory data of pharmaceuticals?

Pharmaceuticals are special goods. It is a universal practice that regulatory clearances must be obtained for pharmaceuticals before market circulation because pharmaceuticals are directly related to human health.[13] To obtain such regulatory clearances (commonly known as "marketing authorization"), pharmaceutical companies are always required to submit the clinical test data generated during the preclinical and clinical testing of a drug, as evidence of its safety, effectiveness and quality.[14] For example, the pharmacokinetic (PK) data is one of the most important clinical test data submitted to the drug administration authorities.

Therefore, in both practice and for the purposes of this article, "regulatory data" refers to the clinical test data submitted to prove a drug's safety, efficacy, and quality in the regulatory approval process. The regulatory data of pharmaceuticals has many synonyms, depending on the context in which it is used. For example, Art.39.3 of the TRIPS Agreement refers to it as "undisclosed test data". In this article, unless otherwise specified, "regulatory data", "undisclosed test data", "test data" and "clinical test data" shall be synonymous. Simultaneously, based on the classifications of pharmaceuticals, such as chemical-entity/small-molecule drugs and biologics, regulatory data of pharmaceuticals can be further categorized into chemical entity drugs regulatory data and biologics regulatory data, a distinction

12 For the sole purpose of this article, "the People's Republic of China", "PRC" or "China" refers to mainland China only, excluding the Hong Kong Special Administration Region, Macao Special Administration Region and Taiwan.

13 *See, e.g,* 21 U.S.C. § 355(a); Yaopin Guanli Fa (药品管理法) [Drug Administration Law] (promulgated by Standing Comm. Nat'l People's Cong., Aug. 26, 2019, effective Dec. 1, 2019), art. 24 (Chinalawinfo) (mandating that drugs must be approved prior to their marketing).

14 *See, e.g,* 21 C.F.R. § 314.50(d)(5) (2025); Yaopin Zhuce Guanli Banfa (药品注册管理办法) [Provisions for Drug Registration] (promulgated by St. Admin. for Mkt. Regul., Jan. 22, 2020, effective July 1, 2020), art. 10(2) (Chinalawinfo) (The applicant shall prove the drug's safety, effectiveness and quality to obtain market authorization for drugs.).

elaborated in Section III.C. below.

B. Why is the regulatory data of pharmaceuticals important?

To understand the importance of regulatory data, its foundational context must be first examined: the generic drug approval pathway, and how such data is utilized within it.

When discussing the generic drug approval pathway regime, a central feature of this regime is the U.S. Drug Price Competition and Patent Term Restoration Act of 1984[15], also commonly referred to as the Hatch-Waxman Act. The Section 505(j) generic approval pathway created by the Hatch-Waxman Act illustrates that regulatory data is important because it can be used by generic companies, if there are no restrictions, to directly apply for the regulatory clearance of generic drugs that further compete with reference drugs in the market, putting brand-name companies' interest at stake.

Prior to the enactment of the Hatch-Waxman Act, a generic company was obligated to submit the clinical test data of its generic-version drugs to the U.S. Food and Drug Administration (FDA) to prove their safety and efficacy in order to receive marketing authorization.[16] The Hatch-Waxman Act has changed this traditional approach and allowed the FDA to approve abbreviated new drug application ("ANDA", *i.e.*, generic drug application) for the marketing of generic versions of brand-name/reference drugs by proving bioavailability and bioequivalence, without repeating costly clinical trials to establish safety and efficacy.[17]

With this Hatch-Waxman Act generic drug approval pathway, the major task that the generic companies need to complete is to prove the bioequivalence between generic drugs and reference drugs.[18] In this process, the test data of reference drugs serves as essential benchmarks in designing a bioequivalence study, which enables the generic companies to experimentally demonstrate that there is no significant difference in the rate and extent of the active ingredient absorption between their generic products and reference drugs, thus establishing the bioequivalence. For example, the PK data of the reference drugs

15 Drug Price Competition and Patent Term Restoration Act, Pub. L. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 15, 21, 35, 42 U.S.C.).

16 Teresa O. Bittenbender & John W. Ryan, *Recent Developments in Pharmaceutical Patent Litigation*, 16(9) INTELL. PROP. & TECH. L. J. 5, 5 (2009).

17 *See 40th Anniversary of the Generic Drug Approval Pathway*, U.S. FOOD & DRUG ADMIN. [hereinafter FDA] (Sept. 23, 2024), https://www.fda.gov/drugs/cder-conversations/40th-anniversary-generic-drug-approval-pathway.

18 *See* 21 C.F.R. § 320.21 (2025). *See also* Ellen 't Hoen, *Protection of Clinical Test Data and Public Health: A Proposal to End the Stronghold of Data Exclusivity*, *in* ACCESS TO MEDICINES AND VACCINES 183, 184 (Carlos M. Correa & Reto M. Hilty ed., 2022).

can facilitate the generic companies' bioequivalence study design and make it easier for the generic products to achieve a pharmacokinetic ratio lying between 0.80 and 1.25, representing a close to the reference standard.[19] In this sense, the test data of the reference drugs is important to generic companies seeking to expedite the market introduction of their generic products.

Accordingly, it is self-evident that regulatory data is also fundamentally important to brand-named/innovative pharmaceutical companies. Following the aforementioned example, once generic companies are able to rely directly on the regulatory data submitted by the original applicant without any extra cost, and obtain regulatory approval, they can significantly save huge amounts of capital expenditures and time otherwise allocated to the research and development (R&D) of their generic products. The saved R&D expenditures allow generic companies to sell generic products at a much lower price to compete with original drugs in the market,[20] which would make it extremely difficult for innovative drug companies to recoup their prior R&D investments and disincentivize the overall new drug R&D.

To balance the interests of both parties, the Hatch-Waxman Act has created the regulatory data protection regime ancillary to the generic drug approval pathway: it grants brand-name drugs (*i.e.*, reference drugs) a 5-year data exclusivity upon FDA approval of a new chemical entity drug (NCE Drug);[21] the FDA cannot approve a generic version of the drug during the data exclusivity period.[22] Particularly, the first three years of this five-year exclusivity constitute an absolute bar to reliance on the test data of the reference drug.[23]

III. ART.39.3 DRAFTING HISTORY AND ITS PROPER INTERPRETATION

A. Enactment of undisclosed test data regime by Art.39.3 of TRIPS Agreement

19 *See* Chittaranjan Andrade, *Bioequivalence of Generic Drugs: A Simple Explanation for a U.S. Food and Drug Administration Requirement*, 76(6) J. CLINICAL PSYCHIATRY 724, 724–25 (2015).

20 *See* Laura J. Robinson, *Analysis of Recent Proposals to Reconfigure Hatch-Waxman*, 11 J. INTELL. PROP. L. 47, 48 (2016) ("[B]ringing a generic drug to market costs only about $1 million, as opposed to the $800 million to $1 billion required to bring a new brand name drug to market").

21 21 C.F.R. § 314.108(b)(2) (2025).

22 *Id.* But if the patent is listed in the FDA publication "Approved Drug Products and Therapeutic Equivalents" (commonly known as "Orange Book"), the FDA will accept such an ANDA or paper NDA filed under 21 U.S.C. § 505(b)(2) on year earlier.

23 21 C.F.R. §314.108(b)(4)–(5) (2025).

Approximately two years after the enactment of the Hatch-Waxman Act, the Ministerial Conference of the General Agreement on Tariffs and Trade (GATT) launched the Uruguay Round of Multilateral Trade Negotiation in Punta del Este, Uruguay, in September 1986. Coincidentally, later that year the European Economic Community (then referred to as the EC) established its own data exclusivity through Directive 87/21/EEC.[24]

The birth of data exclusivity in the U.S. and EC had a profound impact on the drafting of the TRIPS Agreement. At the very beginning of the Uruguay Round, the protection of pharmaceutical test data was not even included as the subject in this Negotiation, as it had never been the subject of any multilateral agreement before.[25] But as time went on to 1990, when virtually all negotiating parties accepted the inevitable inclusion of minimum standards for intellectual property protection in the GATT, the issue of pharmaceutical test data protection became one of the central subjects of the TRIPS Agreement negotiations.[26]

The detailed drafting history of Article 39 of the TRIPS Agreement has been adequately introduced by Mr. Skillington and Mr. Solovy in their joint 2003 article entitled *The Protection of Test and Other Data Required by Article 39.3 of the TRIPS Agreement*[27], which will not be reiterated by this article. Nevertheless, academic discussions on the drafting history of Article 39.3—particularly in relation to pharmaceuticals—have been minimal, if not entirely absent. Hence, it is helpful to present Art.39.3 subject drafting history succinctly.

When the Uruguay Round negotiating parties proposed their draftings in early 1990, the subject of data protection was not even pointed out. The European Economic Community used the word "test or other data"[28], the U.S. used the word "trade secrets"[29], Switzerland used the term "proprietary information"[30], while the proposals from

24 Directive 1987/21 of Dec. 22 1986, amending Directive 65/65/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products, 1987 O.J. (L 15) 36.

25 JAYASHEE WATAL, INTELLECTUAL PROPERTY RIGHTS IN THE WTO AND DEVELOPING COUNTRIES 7 (2001).

26 GATT Secretariat, *Draft Agreement on Trade-Related Aspects of Intellectual Property Rights*, GATT Doc. MTN.GNG/NG11/W/68 (Mar. 29, 1990) [hereinafter 1990 March Draft].

27 G. Lee Skillington & Eric M. Solovy, *The Protection of Test and Other Data Required by Article 39.3 of the TIPRS Agreement*, 24 NW. J. INT'L L. & BUS. 1 (2003).

28 1990 March Draft, at 9–10.

29 GATT Secretariat, *Draft Agreement on the Trade-Related Aspects of Intellectual Property Rights: Communication from the United States*, 14, GATT Doc. MTN.GNG/NG11/W/70 (May 11, 1990).

30 GATT Secretariat, *Draft Amendment to the General Agreement on Tariffs and Trade for the Protection of Trade-Related Intellectual Property Rights: Communication from Switzerland*,

the group of developing countries and from Japan did not contain provisions related to data protection.[31] Even in July 1990, the composite text of an agreement prepared by the Chairman of the Negotiation Group,[32] the wordings in the relevant provisions were still "test or other data"[33] and "clinical or safety tests"[34], without clearly referring to the subject of protection. In fact, it was not until shortly before the Brussels Ministerial Conference held in December 1990 that the subject of test data protection was first articulated, where the Brussels Text[35] provided that:

> *Article 42*
>
> *…*
>
> *4A PARTIES, when requiring, as a condition of approving the marketing of* ***new pharmaceutical products*** *or of a new agricultural chemical product, the submission of undisclosed test or other data, the origination of which involves considerable efforts, shall [protect such data against unfair commercial use. Unless the person submitting the information agrees, the data may not be relied upon for the approval of competing products for a reasonable time, generally no less than five years, commensurate with the efforts involved in the origination of the data, their nature, and the expenditure involved in their preparation. In addition, PARTIES shall] protect such data against disclosure, except where necessary to protect the public.* (emphasis added)

Although the negotiations were not concluded in Brussels mainly due to the failure to reach an understanding on agriculture among negotiating parties, there was commonly agreed upon language of large parts of the agreement, but differences persisted on undisclosed information.[36] After the Brussels Ministerial Conference, progress was made on the protection of test data, particularly in fall 1991,[37] but negotiating parties still used the phrase "pharmaceuticals" as previously used in the Brussels Text.[38] However, this phrase was not

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17–18, GATT Doc. MTN.GNG/NG11/W/73 (May 14, 1990).

31 Skillington & Solovy, *supra* note 27, at 16.

32 GATT Secretariat, *Status of Work in the Negotiating Group: Chairman's Report to the GNG*, GATT Doc. MTN.GNG/NG11/76 (July 23, 1990).

33 *Id.* at 42.

34 *Id.*.

35 GATT Secretariat, *Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Negotiations*, GATT Doc. MTN.TNC/W/35 Rev. 1 (Dec. 3, 1990).

36 A HANDBOOK ON THE WTO TRIPS AGREEMENT 8 (Antony Taubman et al. eds., 2nd ed. 2021).

37 *Id.*

38 GATT Secretariat, *Note by the Secretariat: Meeting of Negotiating Group of 16 and 22 October 1991, Chairman: Ambassador Lars E.R. Anell (Sweden)*, GATT Doc. MTN.GNG/TRIPS/3 (Nov. 18, 1991) ("[L]ikewise, paragraph 4A of the same Article [42] went far

finalized due to the huge disagreement among negotiating parties on other aspects of the TRIPS Agreement drafting.

As time went on to December 1991, the then Director General of the GATT, Mr. Arthur Dunkel, tabled a composite text that he believed to be the most widely acceptable one of an agreement in areas under consideration during the Uruguay Round (commonly known as the "Dunkel Text"[39]). Article 39.3 of the Dunkel Text provided that:

"*Members, when requiring, as a condition of approving the marketing of* ***pharmaceutical*** *or agricultural chemical products* ***which utilize new chemical entities****, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.*" (emphasis added)

The Dunkel Text first used "new chemical entities" in the attributive clause to modify "pharmaceutical" in Article 39.3. More importantly, after the Dunkel Text, there was no more discussion over the subject of test data protection; this expression was directly finalized into the official text of the TRIPS Agreement in 1994.

B. Interpretative Principles

To put it succinctly, the approach of wording interpretation in a treaty can be summed up as follows: (i) if a treaty defines a term, then that definition exclusively governs the term's meaning within the treaty's context, thereby obviating the need for further interpretive analysis; (ii) in the event that the treaty itself does not provide such a definition and the room for interpretation arises, the wording in question will be interpreted by the interpreting authority according to the customary rules of treaty interpretation to the effect that such an interpretation/clarification is regarded as an original part of the treaty, unless it is overridden later on.

Specifically, in terms of the TRIPS Agreement, the World Trade Organization (WTO) adjudicators are mandated to apply the customary rules of treaty interpretation.[40] The WTO Appellate Body

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beyond the limits of reasonable protection which should actually be afforded under national legislation to test data submitted for marketing approval of pharmaceuticals and agro-chemicals") (emphasis added).

39 GATT Secretariat, *Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiation*, GATT Doc. MTN.TNC/W/FA (Dec. 20, 1991).

40 Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, 1869 U.N.T.S. 401, art. 3.2, Annex 2 ("…[to] clarify the existing provisions of those agreements in accordance with customary rules of interpretation of public international law").

and the dispute settlement panels have consistently found that Articles 31 and 32 of the Vienna Convention on the Law of Treaties (VCLT)[41] codify such customary rules, which they must apply.[42]

Article 31 of the VCLT reads that "*A treaty interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in light of its object and purpose.*" With regard to the "ordinary meaning" referred to in Article 31 of the VCLT, the WTO Appellate Body and panels have often relied on dictionary definitions to determine the ordinary meaning of a particular word in practice.[43]

Article 32 of the VCLT further allows the supplementary means of interpretation in limited circumstances, which states that:

Recourse may be had to supplementary means of interpretation, including the preparatory work of the treaty and the circumstances of its conclusion, in order to confirm the meaning resulting from the application of article 31, or to determine the meaning when the interpretation according to article 31:

(a) leaves the meaning ambiguous or obscure; or

(b) leads to a result which is manifestly absurd or unreasonable.

C. Interpretation of Art.39.3

Building on the foregoing approach, the terms "new" and "chemical entities", as used in Art. 39.3, are not defined in the TRIPS Agreement. Therefore, we have to look for whether there has been any clarification over these wordings made by the authority. Under the TRIPS Agreement, the Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS Council) has the authority to clarify or interpret provisions of the TRIPS Agreement. [44] Unfortunately, till the date of this article, the TRIPS Council has never clarified or interpreted "pharmaceutical… which utilized new chemical entities" in Art.39.3. Hence, in order to reach the proper interpretation

41 Vienna Convention on the Law of Treaties, 1155 U.N.T.S. 331 (May 23, 1969) [hereinafter VCLT].

42 *See* Eric M. Solovy, *Protection of Test Data Under Article 39.3 of the TRIPS Agreement: Advancements and Challenges After 25+ Years of Interpretation and Application*, 43 NW. J. INT'L L. & BUS. 55, 69 (2022); Isabelle Van Damme, *Treaty Interpretation by the WTO Appellate Body*, 21 EUR. J. INT'L L. 605, 608 (2010).

43 *See, e.g*, Panel Report, *United States — Section 110(5) of the United State Copyright Act*, ¶¶ 6.108–6.110, WTO Doc. WT/DS160/R, (adopted July 27, 2000); Appellate Body Report, *Canada-Term of Patent Protection*, ¶ 65, WTO Doc. WT/DS170/AB/R (adopted Oct. 12, 2000); Appellate Body Report, *United States-Section 211 Omnibus Appropriations Act of 1998*, ¶¶ 137, 172, 187, 215, WTO Doc. WT/DS176/AB/R (adopted Feb. 1, 2002).

44 *Frequently Asked Questions About TRIPS In The WTO*, WTO, https://www.wto.org/english/tratop_e/trips_e/tripfq_e.htm (last visited June 8, 2025).

of these terms in Art.39.3, it is necessary to examine whether the WTO Appellate Body and panels have applied the customary rules in the VCLT to interpret these terms in TRIPS Agreement Art.39.3-related disputes. Unfortunately, once more, they have not yet had the opportunity to answer this question.

Since the officials have not interpreted these terms, the unsettled question of the meaning of "pharmaceutical… which utilized new chemical entities" has led to two diametric views in academia. The majority believes that biologics regulatory data does not fall into the purview of Art.39.3, [45] as opposed to the minority view that "pharmaceutical… which utilized new chemical entities" is broad enough to cover biologics.[46]

Reading the majority view, it can be found that their arguments are mostly based on policy considerations,[47] to be divorced from solid arguments for treaty interpretation, which is somewhat unconvincing and cannot effectively respond to the minority's argument. To reach a proper interpretation of Art.39.3, this article will summarize the minority view and its arguments first, and conduct a solid interpretation work on Art.39.3 to explain why the majority view ought to be the reasonable and proper one.

1. Minority View: Art.39.3 is Broader Enough to Cover Biologics

The representative view of the minority was put forward by Mr. Solovy in his 2022 article[48]. His arguments can be summarized as follows:

i. In the absence of an official definition and authoritative interpretation of "new", "chemical", and "entity", Art.39.3 must be interpreted by their ordinary meaning (*i.e.*, dictionary meaning) in

45 *See*, *e.g*, Yu, *supra* note 1; Srividhya Ragavan, *The (Re)newed Barrier to Access to Medication: Data Exclusivity*, 51 AKRON L. REV. 1163, 1185 (2017); Pascale Boulet et al., *Data Exclusivity in the European Union: Briefing Documents*, MEDICINES L. & POL'Y (June 2019), https://medicineslawandpolicy.org/wp-content/uploads/2019/06/European-Union-Review-of-Pharma-Incentives-Data-Exclusivity.pdf.

46 *See* NUNO PIRES DE CARVALHO, THE TRIPS REGIME OF ANTITRUST AND UNDISCLOSED INFORMATION 287 (2008) ("[T]he notion of chemical entities covers biotechnology products, including genes and genetically modified genes, for they constitute chemical organic molecules."). *See also* Solovy, *supra* note 42, at 67. ("[T]hus, a "chemical entity" is simply something that is made from or consisting of chemicals. As all matters are made up of chemicals, this is a particularly broad concept.").

47 Yu, *supra* note 1 ("[I]n addition, Article 39.3 of the TRIPS Agreement does not grant protection to biologics because those products are not considered 'new chemical entities' within the meaning of the Agreement."). *See also* Ragavan, *supra* note 45 ("[O]n the face of it, biologics are not included within the scope of Article 39.3's requirement to protect new chemical entities."); Boulet, *supra* note 45 (Table 1 "Limited to new chemical entities (NCEs)").

48 Solovy, *supra* note 42.

good faith with the objective stated by Article 7 of the TRIPS Agreement, which provides that "[T]he protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of the technology knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."[49]; (emphasis added)

ii. The dictionary meanings of "chemical" and "entity", when combined together will lead to his interpretation that "[C]hemical entity is simply something that is made from or consisting of chemical."[50]. Therefore, it is straightforward to see that the notion of chemical entities covers biotechnology products because they constitute chemical organic molecules.[51] Nevertheless, the term "new" shall mean "new within the marketing approval system, rather than a novelty in the patent sense"[52];

iii. Lastly, he concluded that "[A]s explained above, as biologics (like all matters) are composed of chemicals, excluding them from coverage constitutes a violation of Article 39.3 of the TRIPS Agreement."[53]

2. Examine the Minority View

In general, this article believes that Mr. Solovy's interpretation of "pharmaceutical…which utilize new chemical entities" in Art.39.3 is wrong.

Mr. Solovy appears to conflate "ordinary meaning" with "dictionary meaning," even though the WTO Appellate Body and panels have repeatedly emphasized that dictionary definitions, while useful, do not substitute for contextual interpretation.[54]

As the WTO Appellate Body well noted in the US-Offset Act (Byrd Amendment) case: "[D]ictionaries are important guides to, *not dispositive statement of*, definitions of words appearing in agreements and legal document".[55] Hence, relying on dictionary meanings is not a

49 *Id.* at 67.
50 *Id.*
51 *Id.*
52 *Id.* at 75.
53 *Id.* at 88.
54 Van Damme, *supra* note 42, at 622–23. ("[G]enerally, the Appellate Body has not used dictionaries in isolation from the broader context of the treaty language, the context of the dispute, the different uses of particular words or phrases, and the other interpretive elements mentioned in the VCLT").
55 Appellate Body Report, *United States — Continued Dumping and Subsidy Offset Act of 2000*, ¶ 248, WTO Doc. WT/DS238/AB/R (adopted Jan. 16, 2003).

once-and-for-all approach for treaty interpretation, rather dictionary meanings can be challenged or completed in the WTO Appellate Body and panels jurisprudence.[56] Indeed, as many learned judges and distinguished scholars have unequivocally pointed out, which has also been widely accepted by the WTO Appellate Body in its practice, that the dictionary meaning is merely the starting point,[57] and words must be construed by having regard to the context in order to approach their ordinary meaning.[58] As a matter of fact, Mr. Solovy himself does not solely rely on the dictionary meaning to interpret Art.39.3, he might neglect this issue over "chemical entity" in Art.39.3. For example, in his co-authored 2003 article, he and Mr. Skillington first referenced to the Oxford English Dictionary to interpret the meaning of "new" in Art.39.3 as "not existing before", "of a kind now first invented or introduced; novel" or "now known, experienced, used, etc., for the first time".[59] However, the two gentlemen repeatedly emphasized that this dictionary meaning shall not be followed; rather, in light of its context, they argued that "new" ought to refer to the status of a chemical entity within the marketing approval system.[60]

Also, in the WTO Appellate Body and panels jurisprudence, it is noted that law is a specific field of study which induces that "[T]his common use *may be modulated according to contexts*; for example, if the text is a technical matter, *the ordinary meaning of the words will be their technical meaning.*"[61] (emphasis added) Consequently, it shall be pointed out that the word "chemical entity" in Art.39.3 should not be merely interpreted according to its dictionary meaning, repeating the

56 *See* David Pavot, *The Use of Dictionary by the WTO Appellate Body: Beyond the Search of Ordinary Meaning*, 4 J. INT'L DISP. SETTLEMENT 29, 35 (2013). *See also* Appellate Body Report, *United States — Final Countervailing Duty Determination with respect to certain Softwood Lumber from Canada*, ¶ 58, WTO Doc. WT/DS257/AB/R (adopted Jan. 19, 2004).

57 Pavot at 34. *See also* Claus-Dieter Ehlerman & Donald M. McRae, *Reflections on the Appellate Body of the WTO*, 6 J. INT'L ECON. L. 695, 699 (2003). With respect to the Appellate Body's standpoint and practice on this point, see, *e.g.*, Appellate Body Report, *India – Additional and Extra-Additional Duties on Imports from the United States*, ¶ 167, WTO Doc. WT/DS360/AB/R (adopted Nov. 17, 2008); Appellate Body Report, *European Communities – Customs Classification of Frozen Boneless Chicken Cuts*, ¶ 197, WTO Doc. WT/DS269/AB/R, (adopted Sept. 27, 2005); Appellate Body Report, *United States – Final Countervailing Duty Determination with respect to Certain Softwood Lumber from Canada*, ¶ 59, WTO Doc. WT/DS/257/AB/R (adopted Feb. 17, 2004).

58 *See, e.g*, Marco Basile, *Ordinary Meaning and Plain Meaning*, 110 VA. L. REV. 135, 157 (2024); *Yates v United States* 574 U.S. 528, 537 (2015); *HKSAR v Chen Keen* [2023] H.K.C.F.A.R. 11 at [11] *per* Cheung CJ ("[I]t is unhelpful to look at words in a vacuum or to adopt a literal or dictionary meaning of the words being construed, without also paying regard to the context."); Van Damme, *supra* note 54.

59 Skillington & Solovy, *supra* note 27, at 25.

60 *Id.* at 25–26. *See also* Solovy, *supra* note 42, at 66.

61 Pavot, *supra* note 56, at 41.

cliché that "[C]hemical entity is simply something that is made from or consisting of chemical."[62]

3. Proper Interpretation Leads to the Majority View

To reach an appropriate interpretation of "pharmaceutical … utilize new chemical entity", it is crucial to go beyond its dictionary meaning, consider its industrial/technical context and have regard to its negotiating history.[63]

It shall be noted that the phrase "chemical entity" should be interpreted from a broader technical and regulatory context. In Art.39.3, one of the referents it modifies in that attributive clause is "pharmaceutical products". The term "pharmaceutical products" is defined by TRIPS Agreement itself in Annex, which refers to "means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration on the TRIPS Agreement and Public Health.[64]" However, this definition is expressly limited to Article 31*bis* and the Annex, not extended to Art.39.3.[65]

This Article 31*bis*-exclusive definition notwithstanding, the term "pharmaceutical products" provides a good opportunity to understand the pharmaceutical-technical context. In the global pharmaceutical industry, "pharmaceuticals" or "pharmaceutical products" are typically, if not absolutely, classified into two categories, (1) chemical entity drugs and (2) biologics or biological products, and are regulated separately to a large extent, especially in terms of the regulatory approval process. For example, in the U.S., the regulatory framework for pharmaceuticals distinguishes between chemical entity drugs and biologics, with the former regulated under the Food, Drug and Cosmetic Act[66] and the latter under the Public Health Service Act.[67]

62 Solovy, *supra* note 42, at 47.

63 Pavot, *supra* note 56, at 34.

64 Declaration on the TRIPS Agreement and Public Health, WTO Doc. WT/MIN(01)/DEC/2 (Nov. 14, 2001).

65 TRIPS Agreement, Annex ("[F]or the purpose of Article 31*bis* and this Annex.")

66 Food, Drug and Cosmetic Act, Pub. L. No. 75–717, 52 Stat. 1040 (codified as amended in section 21 U.S.C.). 21 U.S.C § 321(g) ¶ (1) defines drug as follows: "(A) articles recognized in the official United States Pharmacopoeia,1 official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C)."

67 Public Health Service Act, Pub. L. No.78–410, 58 Stat. 682 (codified as amended in section 42 U.S.C.). 42 U.S.C. § 262(i) ¶ (1) defines biological products as follows: "a virus, therapeutic

Chemical entity drugs and biological products are generally regulated by different FDA divisions.[68] In the EU, the Directive 2001/83/EC (as amended), which serves as the primary legislation for human medicinal products, differentiates between biological medicinal products and chemical medicinal products based on their respective substance(s).[69] Similarly, the European Medicines Agency (EMA) sets distinct regulatory standards for chemical entity drugs and biological medicinal products.[70] In non-EU European states, such as the United Kingdom (UK) and Switzerland, their laws and regulations also distinguish between chemical entity drugs and biological products.[71] Likewise, in China's pharmaceutical regulatory regime, Article 2, § 2 of the Drug Administration Law delineates two distinct categories: "chemical entity drug" and "biological product".[72] The National Medical Product Administration of China (NMPA), China's principal drug administration authority, also separately defines and regulates "chemical entity drug" and "biological product" within its regulatory approval procedure.[73] In fact, the World Health Organization (WHO)

serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein or analogous product or arsphenamine (or any other trivalent organic arsenic compound) applicable to the prevention, treatment or cure of a disease or condition in human beings."

68 KRISTA HESSLER CARVER, LIFE SCIENCES LAW REVIEW 458 (Richard Kingham ed., 2022). (Center for Drug Evaluation and Research (CDER, FDA) primarily regulates drugs that are typically chemical compounds, while Center for Biologics Evaluation and Research (CBER, FDA) regulates biologics that are generally derived from living cells or organisms).

69 Directive 2001/83, of the European Parliament and of the Council of 6 November 2001 on the Community Code Relating to Medicinal Products for Human Use, art.2, 2001 O.J. (L 311) 67, 73.

70 *See* EUR. MED. AGENCY, *ICH Guideline Q11 on development and manufacture of drug substances (chemical entities and biotechnological/biological entities)*, § 3.1.4, EMA Doc. EMA/CHMP/ICH/425213/2011 (Nov. 2011).

71 *See* The Human Medicines Regulation 2012, SI 2012/1916, art.8(1) ("biological medicine product") (Eng.); Das Bundesgesetz Über Arzneimittel Und Medizinprodukte [Hgm] [Federal Act on Medicinal Products and Medical Devices [TPA]], art. 4(1), Jan. 1, 2002, SR 812.21, (Switz.).

72 Yaopin Guanli Fa (药品管理法) [Drug Administration Law] (promulgated by Standing Comm' Nat'l People's Cong., Aug. 26, 2019, effective Dec. 1, 2019), art. 2(2) (Chinalawinfo) (The term "drugs" as used in this Law refers to substances used to prevent, treat, or diagnose human diseases, purposefully regulate human physiological functions, and have prescribed indications or functions, usage, and dosage, including traditional Chinese medicines, chemical entity drugs, and biological products.).

73 Yaopin Zhuce Guanli Banfa (药品注册管理办法) [Provisions for Drug Registration] (promulgated by St. Admin. for Mkt. Regul., Jan. 22, 2020, effective July 1, 2020), art. 4 (Chinalawinfo). *See also* Guanyu Fabu Huaxue Yaopin Zhuce Fenlei Ji Shenbao Ziliao Yaoqiu Tonggao (关于发布化学药品注册分类及申报资料要求的通告) [Notice on the Release of Chemical Drug Registration Classification and Application Information Requirements] (promulgated by Nat'l Med. Prod. Admin., June 29, 2020, effective July 1, 2020) (Chinalawinfo); Guanyu Fabu Shengwu Zhipin Zhuce Fenlei Ji Shenbao Ziliao Yaoqiu Tonggao (关于发布生物药品注册分类及申报资料要求的通告) [Notice on the Release of Biological Product Registration Classification and Application Information Requirements] (promulgated by Nat'l Med. Prod. Admin., June 29, 2020, effective July 1, 2020) (Chinalawinfo).

suggests that biological therapeutics, or biologicals ought to be regulated, tested, and controlled differently *than other medicines* due to the differences in their nature and how they are produced.[74]

The fundamentally different working principles account for the separate and differing regulatory work of "chemical entity drugs" and "biologics". In summary, "chemical entity drugs" comprise active moieties (typically small molecules) chemically synthesized by human beings. These small active moieties primarily exert therapeutic effects by engaging in biochemical reactions with pathogens, inducing chemical alterations of the physiology of the affected cell, tissue, or organ.[75] Also, chemical entity drugs are too small to be regarded as immunogenic and are typically not recognized by the immune system as "invaders".[76] In contrast, "biologics", extracted from or semi-synthesized from biological sources and containing large molecules[77], result in a higher potential to generate immune reactions: through stronger target design, the human immune system rapidly identifies these kinds of large molecules as non-self and mounts an immune response, typically producing specific antibodies and other proteins to eliminate perceived foreign substances (*e.g.*, pathogens), thereby cure diseases.[78]

This classification, categorical regulations and underlying therapeutic mechanism fully demonstrate that "chemical entity drugs" and "biologics" are two distinct kinds of drug, even though they are under the same larger umbrella of "pharmaceuticals". In light of these circumstances, the pharmaceutical industry often uses "chemical entities" as the abbreviation of "chemical entity drugs", while using "biotechnological/biological entities" as the abbreviation of "biologics".[79]

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74 *Biologicals*, WHO, https://www.who.int/health-topics/biologicals#tab=tab_1 (last visited June 8, 2025).

75 *See* MUHAMMAD AFZAL ET AL., HOW SYNTHETIC DRUGS WORK: INSIGHT INTO MOLECULAR PHARMACOLOGY OF CLASSIC AND NEW PHARMACEUTICALS 12 (Imran Kazmi et al. eds., 2022).

76 *See* Thomas Morrow, *Defining the Difference: What Makes Biologics Unique?*, 1 BIOTECHNOLOGY HEALTHCARE 24, 26 (2004).

77 Biologics can be composed of sugars, proteins, or nucleic acids or complex combinations of these substances, or may be living entities such as cells and tissues. *See What are "Biologics" Question and Answers*, FDA (Feb. 6, 2018), https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/what-are-biologics-questions-and-answers.

78 Morrow, *supra* note 76.

79 *See* International Council on Harmonization of Technical Requirement for Registration of Pharmaceuticals for Human Use (ICH), *Development and Manufacture of Drug Substances (Chemical Entities and Biotechnological/Biologics Entities)*, EMA Doc. EMA/CHMP/ICH/425213/2011 (Feb. 11, 2013). *See also* EMA, *supra* note 70; PHARMACY & POISONS BD. (H.K.), *Guidance Notes on Registration of Pharmaceutical Products Containing a New Chemical or Biological Entity* (Nov. 2024), https://www.ppbhk.org.hk/eng/files/

Therefore, it is reasonable and necessary to consider the sub-category of "pharmaceuticals" when it comes to the pharmaceutical context, particularly when there are terms "chemical entities" in the attributive clause to modify the referent "pharmaceutical". This observation further provides compelling grounds to argue that the term "pharmaceutical…which utilize new chemical entities" in Art. 39.3 shall be given its technical and contextual meaning in the pharmaceutical industry that it refers to "chemical entity drug" only.

The technical context approach under Article 31 of the VCLT is one of the aspects for interpretation, the preparatory work of the treaty also matters because Article 32 of the VCLT allows such work to affirm the meaning derived from the application of Article 31 of the VCLT.

As the Art.39.3-subject drafting history well reflects,[80] the phrase "pharmaceutical … utilize new chemical entities" appeared first time in the Dunkel Text and was directly finalized into the current TRIPS Agreement, no analogous expression had ever been used in earlier drafts or proposals.[81] The most relevant expression could be found in the *Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiation*[82] in the 1990 Brussel Text, Article 42(4A) of which stated that "…as a condition of approving the marketing of new pharmaceutical products …".

It is self-evident that the semantic coverage of "new pharmaceutical products" in the 1990 Brussel Text is significantly broader than that of "pharmaceutical … utilize new chemical entities" in the 1991 Dunkel Text, because the former phrase encompasses both chemical entity drugs and biologics. This change appears to illustrate Mr. Dunkel's intention to narrow down the scope of test data protection to chemical entity drugs only under Article 39.3. However, as Mr. Dunkel passed away in 2005, direct verification of his specific rationale for Art.39.3 wording choosing is no longer possible. Nonetheless, it is still possible to consult other preparatory work to ascertain the reason for this change and explain why "pharmaceutical … utilize new chemical entities" is limited to "chemical entity drug" only.

The broader term "pharmaceutical" in the 1990 Brussels Text was preferred by technology-leading countries because this could provide enhanced intellectual property rights protection for high-end products,

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Guidance_on_Reg_of_Pharm_Prod_Containing_New_Chem_or_Bio_Entity_en.pdf.

80 *See* discussion *supra* Section III.0.

81 In the early 1990s drafting proposals, the subject of test data protection was not even pointed out. *See supra* notes 28–30.

82 GATT Secretariat, *supra* note 32.

including biotechnology.[83] Least-developed countries, however, showed strong resistance to the protection of undisclosed information in the 1990 Brussels Text,[84] and argued that the test data protection went far beyond the limits of reasonable protection.[85] More importantly, it is likely that the WHO's Expanded Program of Immunization around 1990 in developing countries heightened their awareness of the critical role of biologics in public health. These led their delegations to call for a narrower intellectual property commitment and obligation in the Uruguay Round final draft, ensuring that such vaccine biological products and other biological products remain affordable.[86]

Hence, to balance the interests of both developed and developing countries, it is very likely that Mr. Dunkel proposed a mutually acceptable compromise – to confine the scope of test data protection within chemical entity drugs by adding the phrase "utilize new chemical entities" in Article 39.3 of the Dunkel Text – giving the developed countries room to negotiate the biologics regulatory data protection in bilateral, regional and plurilateral trade negotiations,[87] while also enabling developing countries to protect their nascent domestic technological development in biologics.

In conclusion, Mr. Solovy's pure dictionary interpretation of the phrase "pharmaceutical … utilize new chemical entities" is far from a genuine and rational interpretation. Rather, upon examining the contextual interpretation in accordance with the common practice of the pharmaceutical industry and the preparatory work of Art.39.3, this article contends that biologics fall outside the scope of Art.39.3 of the TRIPS Agreement.

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83 *See* Luis Abugattas, *The Uruguay Round of Multilateral Trade Negotiations: Developments and Prospects*, 22 U. MIA INTER-AM. L. REV. 353, 370 (1991) ("[T]he proposals for increased protection are of major concern for the technological leaders. Because technological advances have outpaced the development of intellectual property laws, high-tech products, such as software, semiconductors, and biotechnology, are not effectively protected at the world level.") (emphasis added).

84 *Id.* at 371 (Undisclosed information is a superordinate concept of test data under the TRIPS Agreement regime.).

85 GATT Secretariat, *supra* note 38.

86 *See* GATT Secretariat, *Note by the Secretariat: Meeting of Negotiating Group of 25 and 29 November 1991, Chairman: Ambassador Lars E.R. Anell (Sweden)*, ¶ 7, GATT Doc. MTN.GNG/TRIPS/4 (Dec. 9, 1991) ("[T]hird, least-developed countries should not be required to undertake any commitment or obligation or make least-development status and their trade, development and financial needs. He expressed hope that the Chairman would see to it that this concern be reflected in the final TRIPS text.").

87 Hoen, *supra* note 18, at 189.

IV. BIOLOGICS REGULATORY DATA PROTECTION IN CHINA

A. TRIPS Agreement and China

When China joined the WTO on December 11, 2001, it committed to fulfilling the obligations under the TRIPS Agreement.

To fulfill its obligations, the TRIPS Agreement Art.39.3 obligation in particular, China established its own pharmaceutical regulatory data protection regime in 2002.[88] This regime has granted a 6-year regulatory data protection for "drugs … which contains new chemical entities", where this provision modeled itself on Art 39.3. Although the legal document involved has undergone multiple amendments over the past 23 years, the wording and content of this rule have remained unchanged.[89]

B. The Issue of Biologics Regulatory Data Protection under the PRC Laws

Since China's pharmaceutical regulatory data protection provision is modeled on Art.39.3, the interpretation of Art.39.3 also influences how the pharmaceutical regulatory data protection rule is applied domestically. Following the discussions above, Art.39.3 protects regulatory data of new chemical entity drugs but not that of biologics. Nevertheless, the TRIPS Agreement merely sets out minimum standards for intellectual property rights protection to which all Member States must adhere, and allows Member States to provide more extensive protection if they so wish[90]; thus, an interpretation of the Art.39.3 protection scope cannot conclusively determinate whether China additionally protects biologics test data under its laws.

Fortunately, from the perspective of domestic laws, several official documents and draft regulations issued by the NMPA, which considered or proposed the protection of biologics regulatory data, further indicate that biologics do not fall within the scope of "drugs … which contains new chemical entities" under the Chinese regulatory

88 Yaopin Guanli Fa Shishi Tiaoli (药品管理法实施条例) [Regulations for the Implementation of the Drug Administration Law] (promulgated by St. Council, Aug. 4, 2002, effective Sept. 15, 2002) 2002 ST. COUNCIL GAZ. 27, art. 35 (China).

89 The effective rule governing China's pharmaceutical test data protection, as of the date of this article, is Yaopin Guanli Fa Shishi Tiaoli (药品管理法实施条例) [Regulations for the Implementation of the Drug Administration Law] (promulgated by St. Council, Dec. 6, 2024, effective Jan. 20, 2025) art. 34 (Chinalawinfo) [hereinafter 2024 Regulations for the Implementation of the Drug Administration Law], where its wording is completely same as article 35 of 2002 Regulations for the Implementation of the Drug Administration Law.

90 TRIPS Agreement, Article 1.1.

data protection rules.[91] This manifests that biologics regulatory data is currently not protected in China at present, being consistent with the conclusion by a large number of practitioners in the China Life Sciences & Healthcare sectors.[92]

Nonetheless, China's rules for protecting biologics regulatory data do not conclude at this point. The situation gets more intriguing when the attention is shifted from Chinese domestic laws to international treaties into which China entered, particularly bilateral treaties.[93] The China-Switzerland Free Trade Agreement ("China-Switzerland FTA") is a significant international treaty concerning the protection of biologics regulatory data, Article.11.11 §2 of which unequivocally requires China and Switzerland to grant at least a 6-year regulatory data protection to qualified biologics.[94]

This raises a quintessential issue in international law: when a

91 *See, e.g.*, Guanyu Guli Yaopin Yiliao Qixie Chuangxin Baohu Chuangxin Zhe Quanyi Xiaoguang Zhengce (Zhengqiu Yijian Gao) (关于鼓励药品医疗器械创新保护创新者权益的相关政策(征求意见稿)) [Relevant Policies of the CFDA on Encouraging Innovation in Drugs and Medical Devices and Protecting the Rights and Interest of Innovators (Draft for comments)] (promulgated by China Food & Drug Admin., May. 12, 2017) art. 2 (Chinalawinfo); Yaopin Shiyan Shuju Baohu Shishi Banfa (Zhanxing) (Zhengqiu Yijian Gao) (药品试验数据保护实施办法(暂行)(征求意见稿)) [Implementation Measures for the Protection of Pharmaceutical Trial Data (Interim) (Draft for comments)] (promulgated by Nat'l Med. Prod. Admin., Apr. 25, 2018) (Chinalawinfo); Yaopin Guanli Fa Shishi Tiaoli (Zhengqiu Yijian Gao) (药品管理法实施条例(征求意见稿)) [Regulations for the Implementation of the Drug Administration Law (Draft for comments)] (promulgated by Nat'l Med. Prod. Admin., May 8, 2022) art. 40 (Chinalawinfo); Yaopin Shiyan Shuju Shishi Banfa (Shixing, Zhengqiu Yijian Gao), Yaopin Shiyan Shuju Baohu Gongzuo Chengqiu (Zhengqiu Yijian Gao) (药品试验数据保护实施办法(试行，征求意见稿)、药品试验数据保护工作程序(征求意见稿)) [Implementation Measures for the Protection of Drug Test Data (Interim, Draft for Comments) & Procedures for the Protection of Drug Test Data (Draft for Comments)] (promulgated by Nat'l Med. Prod. Admin., Mar. 19, 2025) Annexes 2 & 3 (Chinalawinfo).

92 *See, e.g, Strengthening Pharma Ip: China's Boost To Data And Market Exclusivity*, BIRD & BIRD LLP (Jan. 24, 2025), https://www.twobirds.com/en/insights/2025/china/strengthening-pharma-ip-chinas-boost-to-data-and-market-exclusivity; *Roche Products (India) Pvt Ltd v. Drugs Controller General of India* (2016) Indlaw DEL 5612, para.293 (India); *Regulatory Data Protection For Pharmaceuticals: How Implementing RDP in China Will Benefit Society, Industry and the Chinese Economy*, COPENHAGEN ECON. (July 2024), https://copenhageneconomics.com/wp-content/uploads/2024/07/Copenhagen-Economics_RDP-for-pharmaceuticals-in-China_JULY2024-_final.pdf.

93 The Chinese government has an obligation to fulfill its international treaty obligations in good faith. *See* Duiwai Guanxi Fa (对外关系法) [Law on Foreign Relations] (promulgated by Standing Comm. Nat'l People's Cong., June 28, 2023, effective July 1, 2023) [hereinafter Law on Foreign Relations], art. 30 (Chinalawinfo); discussion *infra* Section V.0.

94 Free Trade Agreement, China-Switz., art. 11.11(2), July 6, 2013, 1127 U.N.T.S. 411 ("[T]he Parties shall prevent applicants for marketing approval for pharmaceuticals, including chemical entities and biologics, and agricultural chemical products from relying on, or referring to, undisclosed test data or other data submitted to the competent authority by the first applicant for a period, counted from the date of marketing approval, of at least six years for pharmaceuticals and for agrochemical products") (emphasis added).

domestic law and an international treaty have contradictory provisions on the same matter, which one shall prevail? International law jurisprudence presents a theoretical dichotomy here: the Monism and the Dualism posit two opposing answers. In the Chinese legal context, a similar division also exists, [95] and unfortunately, the Chinese authorities have not offered any explicit guidance on resolving this contradiction and the question here is unanswered yet.

However, it appears that the China-Switzerland FTA cannot be directly relied on by a biologics company to assert protection for biologics regulatory data protection in China. This conclusion is drawn from an inference of *The Regulations for the Implementation of the Drug Administration Law (Draft for comments) 2022*, specifically Article 180, which states that "When an international treaty to which the PRC is a party conflicts with Drug Administration Law or this Regulation, such international treaty shall prevail, except for the clauses that the PRC declares to reserve."[96] This provision is the typical practice that China adheres to international treaty obligations, prioritizing international treaties over domestic law in case of conflicting provisions. [97] This drafting provision would protect biologics regulatory data by giving the China-Switzerland FTA precedence over certain Chinese domestic law and regulations. Unfortunately, this drafting provision has been removed from the finalized version --- *2024 Regulations for the Implementation of the Drug Administration Law* , indicating that the Chinese authorities are reluctant to grant international treaties priorities over domestic laws in the field of drug regulation; thus, it is very likely that an applicant cannot argue the precedence of the China-Switzerland FTA and to further seek biologics regulatory data protection in China. Some might argue that the NMPA once assured Swiss stakeholders in 2019 of its commitment to protecting the biologics regulatory data,[98] but it is

95 *See* WANG TIEYA (王铁崖), GUOJI FA (国际法) [INTERNATIONAL LAW] 426 (1995).

96 2024 Regulations for the Implementation of the Drug Administration Law, art. 180.

97 It is a typical provision in the PRC laws stipulating that "*When an international treaty to which the PRC is a party conflicts with this Law, such international treaty shall prevail, except for the clauses that the PRC declares to reserve.*" *See, e.g,* Minshi Susong Fa (民事诉讼法) [Law on Civil Procedure] (promulgated by Standing Comm. Nat'l People's Cong., Sept. 1, 2023, effective Jan. 1, 2024) art. 271 (Chinalawinfo); Nengyuan Fa (能源法) (Energy Law) (promulgated by Standing Comm. Nat'l People's Cong., Nov. 8, 2024, effective Jan. 1, 2025), art. 77 (Chinalawinfo); Kuangchan Ziyuan Fa (矿产资源法) [Mineral Resources Law] (promulgated by Standing Comm. Nat'l People's Cong., Nov. 8, 2024, effective July 1, 2025), art. 79 (Chinalawinfo); Haiyang Huangjing Baohu Fa (海洋环境保护法) [Marine Environment Protection Law] (promulgated by Standing Comm. Nat'l People's Cong., Oct. 24, 2023, effective Jan. 1, 2024), art. 123 (Chinalawinfo); Minyong Hangkong Fa (民用航空法) [Civil Aviation Law] (promulgated by Standing Comm. Nat'l People's Cong., Apr. 29, 2021, effective Apr. 29, 2021), art. 183 (Chinalawinfo).

98 *Contra IP Dialogue China-Switzerland 10th Meeting of The Intellectual Property Rights*

important to point out that this NMPA response falls outside the legal and normative framework and is not binding on itself because the doctrine of legitimate expectation [99] is absent under China's administrative law.

V. SHOULD BIOLOGICS REGULATORY DATA BE PROTECTED IN CHINA?

Since China's present regulatory data regime does not extend to biologics, a crucial *de lege ferenda* question arises: should biologics regulatory data be protected in China?

To assess whether China should introduce regulatory data protection for biologics, three key questions must be considered: (A) whether patent alone suffices to safeguard reference biologics? (B) can biologics regulatory data protection rules promote the development of innovative biologics and thus benefit public health? (C) is there a need for China to align with international practice to protect biologics regulatory data?

A. Insufficient patent protection to biologics

Patent protection, as a form of artificial monopoly, enables a patent proprietor to exclude others from making, using and selling the patented innovation for a specified duration. Therefore, patents have been widely used as a key tool by brand-name pharmaceutical companies to postpone entry of follow-ons.[100] Research indicates that, in the U.S., biologics possessed a median of 14 patents per product, in contrast to 3 patents per chemical entity drug. Furthermore, brand-name biologics companies have claimed infringement of 12 times more patents per litigated product than chemical entity companies.[101] Given these facts, one may question: why biologics regulatory data protection

Working Group (9th to 12th September 2019), MINISTRY OF COM. OF CHINA, www.swisscham.org/beijing/wp-content/uploads/sites/2/2018/04/IP-Dialog-China-Switzerland-2019-Technical-Questions-Answers-for-Swiss-Industry.pdf. (last visited Apr. 23, 2024).

99 In the UK and among the commonwealth jurisdictions, the doctrine of legitimate expectation is a ground for judicial review in the administrative law, set by the UK House of Lords in *Council of Civil Service Unions v Minister for the Civil Service* [1985] AC 374 (appeal taken from Eng.). In summary, the doctrine of legitimate expectation holds that where a decision-maker leads a person affected by a decision legitimately to expect either that a particular procedure will be followed in reaching a decision or that a particular (and generally favorable) decision will be made (and such decision would be within his power), then, save where there is an overriding public interest, that legitimate expectation must be protected.

100 *See* Oliver J. Wouters et al., *Differential Legal Protections for Biologics vs Small-Molecule Drugs in the US*, 332(24) J. AM. MED. ASS'N 2101, 2105 (2024).

101 *Id.* at 2104–5.

is necessary if patents offer adequate and robust protection for biologics?

In the first place, when discussing patent protection of biologics, it is essential to consider patent law at the global level, as numerous China-approved therapeutical biologics are overseas-marketed biologics[102] (especially applications who are European and American pharmaceutical giants or their wholly-own Chinese subsidiaries[103]), most of which are covered by European and American patents and it is feasible to designate China in international patent applications submitted through the Patent Cooperation Treaty (PCT)[104] route. Hence, this section will examine patent laws in the U.S., UK, EU and China in this part (hereinafter referred to as "considered jurisdictions").

1. Patentability of Biologics

A biologic is a large molecule typically derived from living cells, used in the treatment, diagnosis or prevention of disease, including therapeutic proteins, DNA vaccines, monoclonal antibodies, and fusion proteins. The distinctive characteristics of biologics raise an immediate concern regarding their patent protection: the patentability of biologics. The reason for this concern is that among considered jurisdictions, such as the U.S., EU and China, authorities have almost unanimously determined that naturally occurring products, such as human DNA and proteins, are not *per se* patentable.[105]

The leading case is the U.S. Supreme Court decision in *Ass'n for Molecular Pathology v. Myriad Genetics*. In *Myriad*, the U.S. Supreme Court identified a claimed full-length complementary DNA (cDNA) of the BRCA1 gene as a nature-based product having markedly different characteristics. This claimed cDNA exhibited identical

102 *E.g.* in 2023, 29 of 64 approved (45.31%) therapeutic biological products are Class 3.1 biologics (*i.e.*, manufactured and marketed overseas, and applying for marketing authorization in China), *see* Xiecheng Zhi et al., *Approvals by the China NMPA in 2023*, 23(3) NAT. REV. DRUG DISCOVERY 164, Supplementary Table 1 (2024); in 2024, 32 of 93 approved (34.41%) therapeutic biological products are Class 3.1 biologics, *see* Xiecheng Zhi et al., *Approvals by the China NMPA in 2024*, 24(3) NAT. REV. DRUG DISCOVERY 160, Supplementary Table 1 (2025).

103 Zhi et al., *Approvals by the China NMPA in 2023*, 82.76% (24/29) of the approved Class 3.1 biologics in 2023 were by European and American pharmaceutical giants or their wholly-owned Chinese subsidiaries.

104 28 U.S.T. 7645 (1976).

105 *See, e.g.*, *Ass'n for Molecular Pathology v. Myriad Genetics 133* U.S. 2107 (2013); *Human Genome Sciences Inc v Eli Lily & Co* [2011] UKSC 51 (appeal taken from Eng.); Directive 98/44/EC, of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions, arts. 5(1), 6(2)(a)–(b), 1998 O.J. (L 213) 18; Zhuanli Shencha Zhinan (专利审查指南) [Patent Examination Guidelines] (promulgated by China Nat'l Intell. Prop. Admin., Dec. 21, 2023, effective Jan. 20, 2024), pt. II, § 9.4.1.

functional attributes (*i.e.*, it encoded the same protein) as the naturally occurring gene, yet had a changed structural characteristic, *i.e.*, a different nucleotide sequence containing only exons, as compared to the naturally occurring sequence containing both exons and introns. The U.S. Supreme Court first clarified that the naturally occurring products are not *per se* patentable, however, it further concluded that the "cDNA retains the naturally occurring exons of DNA, but it is distinct from the DNA from which it was derived. As a result, [this] cDNA is not a 'product of nature'." and is eligible for patent protection.[106] This landmark case reveals that the essential criterion for assessing the patentability of a biologic is the presence of alterations in characteristics that result in a significant distinction.[107]

As for the universality of "significant distinction" in the patent law, the U.S. Federal Trade Commission (FTC) observed that there is scant evidence suggesting that biological drugs under development are unpatentable. The FTC further noted that pioneer biologic drugs are covered by a broader and more diverse array of patents, including those related to manufacturing and technology platforms, compared to small-molecule branded products.[108] Although the foregoing FTC report supports the patentability of biological products, it does not fully alleviates concerns regarding the limited patent protection for biologics, as their package patents remain susceptible to challenges in patent litigation. The question of creativity remains significant. Taking *Novonesis and Jiangsu Boli Biological Products Co., Ltd. v. Patent Reexamination Board of China National Intellectual Property Administration* ("*Novonesis Case*")[109] as an example, the applying patent in issue was the "Thermostable Glucoamylase", as part of a manufacturing patent for its later biological products. The PRC Supreme People's Court held that the actual technical problem solved by the applied patent pertained to providing glucoamylase with various sources and molecular weights, which did not provide any inspiration for solving that problem. The appellant Novonesis's argument that it enhances thermal stability in comparison to a similar U.S. patent is

106 *Myriad* at 595. *See also* 106 USPQ2d at 1981.

107 *Myriad* at 580; *see also* 106 USPQ2d at 1974–75.

108 *See Emerging Healthcare Issues: Follow-On Biologic Drug Competition*, U.S. FED. TRADE COMM'N (June 2009), https://www.ftc.gov/sites/default/files/documents/reports/emerging-health-care-issues-follow-biologic-drug-competition-federal-trade-commission-report/p083901biologicsreport.pdf.

109 Guojia Zhishi Chanquan Jü Zhuanli Fushen Weiyuan Hui Nuowei Xin Gongsi Yü Jiangsu Boli Shengwu Zhipin Youxian Gongsi Faming Zhuanli Quan Wuxiao Xingzheng Jiufen Zaishen An(国家知识产权局专利复审委员会、诺维信公司与江苏博立生物制品有限公司发明专利权无效行政纠纷再审案) [Novonesis and Jiangsu Boli Biological Products Co., Ltd. v. Patent Reexamination Bd. of China Nat'l Intell. Prop. Admin., A Retrial Over Patent Infringement], 行政判决书(2016)最高法行再 85 号, (Sup. People's Ct., 2016).

irrelevant to the question of creativity. As a result, the Court held that this applying patent product did not significantly differ from naturally occurring products and therefore did not meet the patentability criteria of creativity. Beyond the issue of creativity, biologics patents also face the question of the sufficiency requirement under the patent law. The sufficiency requirement mandates that the patentee, if challenged, must demonstrate that a skilled person can make the product by the use of the teaching disclosed in the patent coupled with the common general knowledge which is already available as of the priority date, without incurring an excessive experimental burden or exercising inventiveness of their own. [110] For instance, in *Regeneron Pharmaceuticals Inc v Kymab Ltd*[111], the UK Supreme Court upheld Kymab's appeal by a majority of four to one, holding that Regeneron's biologics patent was invalid for insufficiency because the claim range went far beyond the contribution and the more valuable end of the range could not be made, using the existing disclosure in the patent.[112] Similarly, biologics patents have encountered the same question of sufficiency in the U.S.[113] On a final note, even though biologics are not unpatentable and can be safeguarded by various manufacturing and technology platform patents, the concerns regarding the patentability of biologics, especially pioneering ones, and their susceptibility in patent proceedings still wander due to their inherent characteristics.

In stark contrast to the abovementioned shortcoming of biologics patent protection, the granting of biologics regulatory data protection is not contingent upon patent criteria such as creativity and sufficiency description; rather, it is automatically conferred for a specific duration, so long as such biologics are approved for marketing as "first-in-class".[114]

2. Limited Patent Term and Patent Term Extension for Biologics

The second imminent issue following patentability is the term of

110 *Infra* note 111, at [2].

111 [2020] UKSC 27 (appeal taken from Eng.).

112 *Id.* at [57].

113 *See, e.g, Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330 (Fed. Cir. 2021); Christopher M. Holman, *In Juno v Kite the Federal Circuit Strikes Down Patent Directed Towards Pioneering Innovation in CAR T-Cell Therapy*, 40 BIOTECHNOLOGY L. REP. 372, 378 (2021) ("[T]he panel held that no reasonable jury could find the '190 patent's written description sufficiently demonstrates that the inventors possessed the full scope of the claimed invention, and that substantial evidence did not support the jury's finding of adequate written description for any of the asserted claims.").

114 *See, e.g*, 42 U.S.C. §262(k)(7)(A); Directive 2004/27/EC, of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (Text with EEA relevance), 2004 O.J. (L 136) [hereinafter Directive 2004/27/EC].

patent protection. A patent's life begins at the date of patent application filing, which often occurs well in advance of the initiation of clinical trials, leading to a diminished patent lifespan by the time the pharmaceutical products is marketed.[115] To provide a clearer illustration, let us establish a series of assumptions as follows:

i. A biologics company submits a biologics patent application and concurrently secures an investigational new drug approval in the U.S. (noted: this assumption is near impossible in reality due to the typically prolonged interval between patent application and Phase I clinical trial)

ii. The entire clinical trials and regulatory approval of such biologics cost 12.6 years (a median figure).[116]

Article 33 of the TRIPS Agreement requires its Member States to grant patents for a period of not less than 20 years, and considered jurisdictions have unanimously embraced the 20-year patent protection. Thus, the post-approval patent life would be 7.4 years or potentially shorter due to more stringent regulations over the biological product applications.[117] However, the 7.4 years are far from ideal because the empirical and economic study suggests that it takes nearly 14.3 years for biologics developers to recoup their R&D investments, provided that there is no biosimilar entry.[118]

Some might defend that the patent term extension (PTE), a regulatory mechanism to compensate pharmaceutical companies for patent term loss due to unfair regulatory delay during the regulatory approval process, would assist the patentee in extending the patent duration.[119] In the best PTE case scenario, the post-approval patent lifespan can only extend to a maximum of 12.4 years (7.4-year of remaining patent life plus a 5-year PTE[120]), which remains insufficient still difficult to reach the ideal range of 12.9-16.2 years.[121] Moreover, in

115 Kristina M. Lybecker, *Essay: When Patents Aren't Enough: Why Biologics Necessitate Data Exclusivity Protection*, 40(4) WM. MITCHELL L. REV. 1427, 1428 (2014).

116 Wouters et al., *supra* note 100, at 2103.

117 FDA, *supra* note 77. ("[B]iological products, including those manufactured by biotechnology, tend to be heat sensitive and susceptible to microbial contamination. Therefore, it is necessary to use aseptic principles from initial manufacturing steps, which is also in contrast to most conventional drugs.").

118 Henry Grabowski et al., *From the Analyst's Couch: Data Exclusivity for Biologics*, 10 NAT. REV. DRUG DISCOVERY 15, 15 (2011).

119 *See, e.g*, 35 U.S.C. § 156; Regulation 469/2009, of the European Parliament and of the Council of 6 May 2009 Concerning the Supplementary Protection Certificate for Medicinal Products [hereinafter Regulation 469/2009], art. 2, 2009 O.J. (L152) 2; Zhuanli Fa (专利法) [Patent Law] (promulgated by the Standing Comm. Nat'l People's Cong., Oct. 17, 2020, effective June 1, 2021) [hereinafter Patent Law], art. 42(3). (Chinalawinfo).

120 The aggregated patent extension term may not exceed 5 years. *See* 35 U.S.C. § 156(g)(6)(A)–(B); Regulation 469/2009, art. 13(2); Patent Law, art. 42(3).

121 *See* Joseph A. Dimasi & Henry G. Grabowski, *The Costs of Biopharmaceutical R&D: Is*

all cases, the law explicitly states that the total patent life for the product with the patent extension cannot surpass 14 years from the product's approval date, thereby allowing a maximum of 14 years of potential marketing time.[122] Indeed, as previously stated, the PTE mechanism is designed to restore the period of the FDA regulatory approval process: the PTE granted by the U.S. Patent & Trademark Office (USPTO) is not entirely discretionary, rather it is contingent on actual circumstances and largely depends on the clinical trial and regulatory approval phrases.[123] A recent study shows that the average biologics PTE time in the U.S. is 1,057 days (approximately 2.9 years).[124] Consequently, the post-clearance patent life can be plausibly estimated at 10.3 years, which remains below the optimal duration.

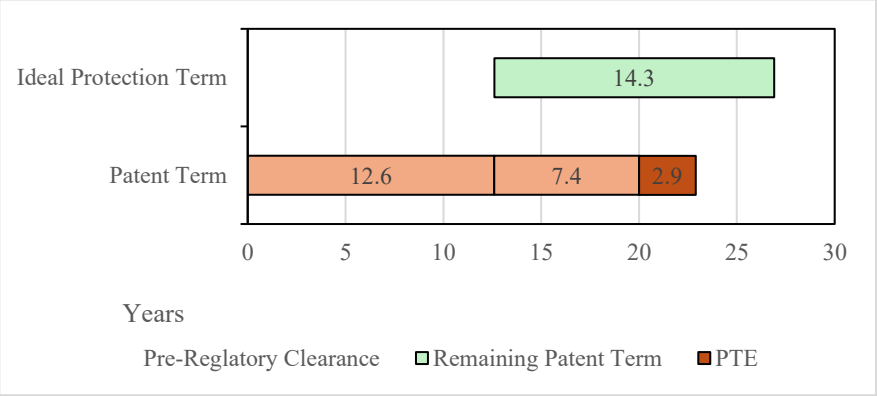

Figure 1. Ideal Protection Term and Patent Term

A more significant challenge lies in the inadequacy of patent protection duration: not all biologics, even if those pioneering biologics

Biotech Different?, 28 MGMT. DECISION ECON. 469, 476 (2007). *See also* Grabowski et al., *supra* note 118.

122 *Small Business Assistance: Frequently Asked Questions on the Patent Term Restoration Program*, FDA (Feb. 4, 2020), https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/small-business-assistance-frequently-asked-questions-patent-term-restoration-program#:~:text=In%20all%20cases%2C%20the%20total%20patent%20life%20for,other%20words%2C%2014%20years%20of%20potential%20marketing%20time.

123 *See* 21 C.F.R. § 60.20(a). ("FDA will consult its records and experts to verify the dates contained in the application and to determine the length of the product's regulatory review period under § 60.22. …"); *id.* § 60.22 (In determining a product's regulatory review period, […] FDA will review the information in each application using the following definitions of the testing phase and the approval phase for that class of products.).

124 *See* C. Benson Kuo and Frances Richmond, *Use of Patent Term Extensions to Restore Regulatory Time for Medical Devices in the United States*, 21 EXPERT REV. MED. DEVICES 527, 528–29 (2024).

that can justify themself most in anticipating a PTE, may qualify themselves for a PTE. According to statistics, between 2015 and 2021, merely 53.4% (47/88) of innovative therapeutic biological products were granted with PTE in the U.S., 63.9% (62/98) of innovative therapeutic biological products were granted with PTE in the EU and only 15.4% (2/13) of innovative therapeutic biological products were granted with PTE in China.[125]

The phenomenon occurs because PTE is exclusively available for the active ingredient of a pharmaceutical products formulation.[126] The defining "active ingredient" in relation to biologics remains ambiguous, despite the U.S. Federal Circuit has addressed the question of what constitutes an active ingredient several times in the context of small molecule drugs.[127] It is uncertain how the court will apply the current case law and statutory provisions to biologics.[128] YESCARTA®, a CAR-T-cell cancer therapy for B-cell lymphoma, exemplifies the challenges associated with defining and applying of "active ingredient" in biologics PTE applications.[129] In the Yescarta® PTE Application case, the applicant Cabaret Biotech Ltd. submitted a PTE application over the patent of an autologous T cells drug on December 14, 2017, initially asserting the engineered T cells as the active ingredient. However, after the USPTO denied Cabaret's application, explaining that the cell could not be considered as the active ingredient because of their variability among patients, and determined the chimeric antigen receptor was not an active ingredient.[130] After joint efforts by

125 Du Xin et al (杜鑫等), *Zhiliao Yong Xin Shengwu Zhipin Zhuanli Yu Shiyan Shuju Xietong Baohu Jianguan Kaoliang* (治疗用新生物制品的专利与试验数据协同保护的监管考量) [*Regulatory Considerations for Synergistic Protection of Patents and Data Exclusivity for Innovative Therapeutic Biologics*], 31(24) Zhongguo Xinyao Zazhi (中国新药杂志) [CHINESE J. NEW DRUGS] 2413, 2416 (2022).

126 *See, e.g*, 21 C.F.R. § 60.3(b)(10) (definition of human drug product); *id.*, § 60.10(a)(2) (eligibilities of human drug product); Regulation 469/2009, art.1 ¶(b).

127 21 C.F.R. § 60.3(b)(2) defines "active ingredient" as "any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or of animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect."; the U.S. Federal Circuits have addressed the question of active ingredients in the context of small molecules. *See, e.g*, *Glaxo Operations UK Ltd. v. Quigg*, 894 F.2d 392 (Fed. Cir. 1990); *Pfizer Inc. v. Dr. Reddy Labs. Ltd.*, 359 F.3d 1361 (Fed. Cir. 2004).

128 *See* Nicholas G. Vincent, *Patent Term Extension and the Active Ingredient Problem*, 9 N.Y.U. J. INTELL. PROP. & ENT. L. 279, 296 (2020) ("[I]n short, the current framework for determining the active ingredient of a pharmaceutical or therapeutic product for purposes of patent term extension is not easily applied beyond chemical compounds and salt formulations.").

129 *Id.* at 303.

130 *See* Requirement for information sent under 37 C.F.R. § 1.750, U.S. Patent No. 7,741,465 (Apr. 3, 2018). *See also* Second letter to regulating agency to determine regulatory review period, U.S. Patent No. 7,741,465 (Aug. 7, 2018).

Cabaret and federal agencies, the USPTO eventually granted a PTE to Cabaret over YESCARTA® on May 6, 2021 on the basis that YESCARTA® DNA sequences differed from previously approved antibody and constitute a new active ingredient. This case effectively illustrates that the USPTO remains receptive to examining the definition of an active ingredient in advanced biological products, requiring the FDA's further interpretation of "active ingredient" concerning the initial authorized commercial marketing of biologics, as well as the court's ruling on how the term "active ingredient" is interpreted within the framework of extended-term patents for biologics. The ambiguities created by drug regulatory agencies and judicial bodies further underscore the inadequacies in patent protection for biologics.

As regards protection times, regulatory data protection outperforms patent protection with respect to biologics: (i) the data protection period commences upon market clearance of the biologics, (ii) the data protection period is fixed by statute,[131] rather than at some discretion of patent-granting agencies (in terms of PET). (See Figure 2 below for a more intuitive comparison of (i) and (ii)) and (iii) data protection is more assured for advanced and innovative therapeutical biologics because a first-in-class biologic is always eligible for such protection, irrespective of the "active ingredient" it contains, meaning that a scenario akin to the Yescarta® case would never happen under biologics regulatory data protection regime.

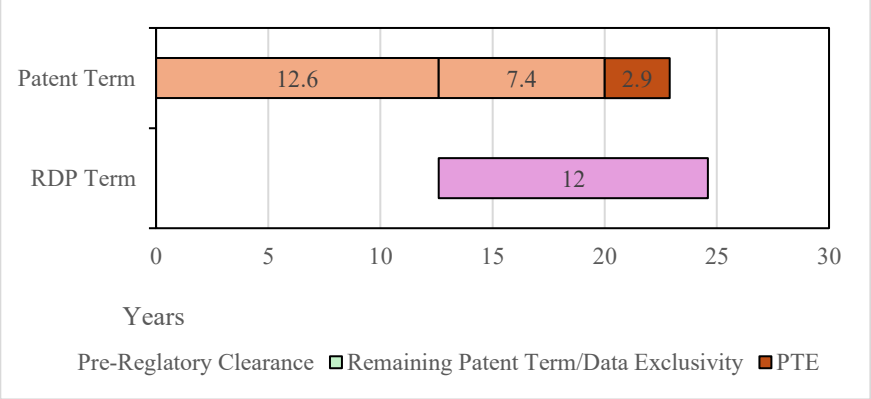

Figure 2. Comparison between Patent and RDP Terms

131 U.S. grants qualified biologics a 12-year exclusivity according to 42 U.S.C. § 262(k)(7)(A), the EU grants qualified biologics "8+2+1 years" data exclusivity according to Directive 2004/27/EC.

3. Intrinsic Drawbacks of Biologics Process Patent

Finally, but most fatally, biologics patents are more susceptible to subsequent "work-around" patent innovations than those for small molecule drugs.[132]

As mentioned above, biologics are large complex molecules extracted from living organism, which leads to two important matters that (i) unlike the generic chemical entity drug approval pathway where generic companies have to demonstrate their product is as "same" as the innovator drug through proving bioequivalence, it is virtually impossible for a generic company to establish that its follow-on biologic is identical to a reference biologic,[133] consequently drug regulatory authorities require only "highly similar" in the biosimilar approval pathway,[134] and (ii) biologic developers rely on more on process patents because "[P]rocesses by which biologicals are made are highly specific, complex, and determine many of the biologic's functional and structural characteristics … that can often be expected to affect the product's safety, purity, and efficacy profile, and thus are integral to the approval of the product itself."[135] These two matters prompt generic companies to realize that they may "work-around" the process patents of reference drugs to circumvent patent protections while still attaining "similarity" in the biosimilar approval pathway.

To counter the foregoing strategy employed by biosimilar companies, brand-name biologics companies attempt to patent a broader process to make it harder for biosimilar companies to elude patent infringement.

Considering that the subject of process patents encompasses (a) the process itself and (b) the products produced by such process, the very first step that brand-name biologics companies will do is to include as many variants as possible in their patent applications, making it easier for biosimilar companies to enter the "minefields" of patent protection. Nonetheless, as Professor Christopher noted, it is unreasonable to expect a patent prosecutor to draft a claim literally encompassing all biomolecule equivalents.[136] As for China's practice,

132 Henry G. Grabowski, *Data Exclusivity for Biologics: What is the Appropriate Period of Protection?*, AM. ENTER. INST., RSCH. REP. No. 10 (Sept. 2009), https://www.aei.org/research-products/report/data-exclusivity-for-biologics-what-is-the-appropriate-period-of-protection/.

133 *See* Bruce S. Manheim JR et al., *'Follow-On Biologics': Ensuring Continued Innovation In The Biotechnology Industry*, 25(2) HEALTH AFF. 394, 397 (2006).

134 *See, e.g.*, 42 U.S.C. § 262(k); Directive 2001/83/EC, art. 10(1)(a).

135 *BIO Comments to Project No. P083901 (Health Care Competition)*, BIOTECHNOLOGY INDUSTRY ORGANIZATION (Sept. 30, 2008), https://www.ftc.gov/sites/default/files/documents/public_comments/emerging-health-care-competition-and-consumer-issues-537778-00013/537778-00013.pdf.

136 Christopher M. Holman, *Ajinomoto v. ITC, the Doctrine of Equivalents, and Biomolecule*

this thorny issue was also highlighted by the PRC Supreme People's Court in the *Novonesis Case*. In *Novonesis Case*, another core issue is: if experimental evidence proves that a certain enzyme and a variant which meets some specific requirement can achieve the purpose of the invention, then in addition to the aforesaid enzyme and its variant, can the scope of protection of the patent claim be extended to other variants of that enzyme. The PRC Supreme People's Court has made it clear that a person skilled in the field is unable to ascertain whether other variants would possess the enzyme-activity if the scope were arbitrarily extended without first identifying the structure-function relationship of that enzyme. Consequently, it is evident that it is impractical, if not challenging, for process patent holders to encompass numerous biomolecule variants within the scope of patent protection in China.

It should be noted that a wider patent description is one of the strategies to block follow-ons, the doctrine of equivalents (DOE) under the patent law is usually invoked by brand-name pharmaceutical companies to eliminate potential "work-around" patent threats either. In general, the DOE allows a patent holder to assert infringement claims even if not all elements of the patented invention are identically present in the accused product, with the objective of preventing infringers from appropriating the advantages of a patented invention by making only trivial or inconsequential modifications while preserving the same functionality.

Although the DOE is thought to offer patent holders extensive protection against competitors making minor alterations,[137] this equitable doctrine is inherently restrictive and seldom succeeds concerning biologics process patents in considered jurisdictions

The valuable insight into the self-limiting nature of DOE has been pointed out by the U.S. Court of Appeals for the Federal Circuit in *Amgen Inc. v. Sandoz Inc.*[138] In this underlying litigation, Amgen disputed with Sandoz over a biosimilar version of Amgen's filgrastim (Neupogen®) and pegfilgrastim (Neulasta®) biologics. Specifically, Amgen accused that Sandoz's '878 patent, a method of protein

Claim Limitations at the Federal Circuit, 39 BIOTECHNOLOGY L. REP. 3, 17 (2020).

137 *See* Nicholas Pumfrey et al, *The Doctrine of Equivalents in Various Patent Regimes – Does Anybody Have It Right?*, 11 YALE J. L. & TECH. 261, 307 (2009) ("[T]he United States arguably provides the broadest protection under the doctrine, counting foreseeable equivalents as infringing so long as they are not equivalent to an amended aspect of a claim, and unforeseeable equivalents as always infringing – with the caveat that unforeseeable equivalents have difficulty passing the "way" aspect of the equivalent test."). *See also Actavis v Eli Lily* [2017] UKSC 48 (appeal taken from Eng.) at [66] (where the UK Supreme Court formulates its own doctrine of equivalents test, capable of catching broad equivalents in English law).

138 *Amgen Inc. v. Sandoz Inc*, 923 F.3d 1023 (Fed. Cir. 2019).

purification, infringed Amgen's '427 patent on the basis of equivalents. Circuit Judge Lourie, after careful consideration of the claim disclosures of these two patents, agreed with the district judge's analysis that Sandoz's one-step, one-solution process accomplishes purification in a different way from the claimed method and thus, is not equivalent.[139] Besides, his honor pointed out that the claim in Amgen's '427 patent was not broad enough to cover every possible method of separating a specific protein from other solutes.[140] More importantly, his honor emphasized that "the doctrine of equivalents applies only in exceptional cases and is no 'simply the second prong of every infringement charge, regularly available to extend protection beyond the scope of the claims.',[141] indicating that the Federal Circuit is walking back its "exceptional" stance on DOE.[142] Likewise, as reflected by the PRC Supreme People's Court's decision in *Sino-Swed Tongkang Biotechnology (Shenzhen) Co., Ltd v. Nanjing Norman Biological Technology Co., Ltd.*,[143] it is challenging, for patent holders of biologics processes to demonstrate infringement of subsequent biosimilars via the DOE in China. In this case, the appellant Sino-Swed Tong Kang (as the claimant in the first instance), as the patent holder of ZL201110353971.0, a process patent to manufacture a highly specific and sensitive multi-epitope anti-human TK1-IgY combination antibody, accused the respondent Nanjing Norman's infringed its process patent by manufacturing the alleged infringing product (i.e., *Thymidine Kinase 1 Detection Kit*) based on process equivalents. The PRC People's Supreme Court held that the antibody contained in the alleged infringing product was extracted from hens, as opposed to the protected antibody extracted from laboratory mice, therefore, the accused process had already qualified itself as a substantially different manufacturing process. Moreover, the appellant fails to prove to the court that the preparation of the antibody by different living bodies (hen versus laboratory mice) is a technical feature that the function-way-result are basically the same for people skilled in the art.

Admittedly, some courts within the considered jurisdictions have

139 *Id.* at 1029.

140 *Id.*

141 *Id.*

142 *London v. Carson Pirie Scott & Co.*, 946 F.2d 1553, 1538 (Fed. Cir. 1991) ("[N]oting that if the doctrine of equivalents is not the exception but rather the rule, the public will come to "believe (or fear) that the language of patent claims can never be relied on." ").

143 Huarui Tongkang Shengwu Jishu (Shenzhen) Youxian Gongsi, Nanjing Nuoerman Shengwu Jishu Gufen Youxian Gongsi Qinhai Faming Zhuanli Quan Jiufen (华瑞同康生物技术(深圳)有限公司、南京诺尔曼生物技术股份有限公司侵害发明专利权纠纷) [Sino-Swed Tongkang Biotechnology (Shenzhen) Co., Ltd v. Nanjing Norman Biotechnology Ltd., A Dispute over Patent Infringement], 2020 SUP. PEOPLE'S CT. GAZ. 342 (China).

already successfully extended the DOE to biologics process patents in rare cases,[144] but the DOE strategy is still rather uncertain and extremely constrained within the broader picture of biologics intellectual property protection.

Brand-name biologics companies, however, do not have foregoing concerns when it comes to biologics regulatory data protection: in the U.S. for example, the reference exclusivity blocks the submission of a biosimilar application for 4 years,[145] and blocks approval of biosimilar application for 12 years from the date of the first approval,[146] unless such biosimilar makes a supplement to the reference biologics (*e.g.*, to change the original conditions of use).[147] This mechanism offers significant protection for first-in-class biologics, potentially excluding all "work-around" biosimilars targeting the same indication from the market.

B. Benefits to biologics innovation and contribution to public health

As Professor Peter K. Yu well noted in his article, it is difficult to determine *ex-ante* whether stronger protection in the ever-evolving biotechnology field would accelerate or stifle the future development of biologics.[148] He therefore suggested policymakers enacting the protection of the biologics regulatory data only when the empirical study proves the necessity of doing so.[149]

China does not have its own biologics regulatory data protection regime. Thus, it will be helpful to first review overseas empirical studies, especially empirical studies in the U.S., to explain why the biologics regulatory data protection regime would contribute to biologics innovation and benefit public health at large.

1. Incentives for Innovation

The first research object is the Orphan Drug Act,[150] which allows the FDA to grant a 7-year data exclusivity to drugs designated and approved to treat disease or conditions affecting fewer than 200,000 in the U.S. (or more than 200,00 and not hope of recovering cost).[151] With

144 *See, e.g.*, Hof Hague 15 november 2022, ECLI:NL:RBDHA:2022:7186, (Pharmathen Global BV/Novartis AG (Neth.).

145 *See* 42 U.S.C. § 262(k)(7)(B).

146 *Id.* at (A).

147 *Id.* at (C)(i).

148 Yu, *supra* note 1, at 690.

149 *Id.* at 691.

150 Pub. L 97–414, 96 Stat. 2049 (1983) (codified as amended in scattered sections of 21, 26 and 42 U.S.C.).

151 *See* 21 § C.F.R. 316.31.

this incentive created by data exclusivity, within 5 years from the enactment of the Orphan Drug Act, a total of 197 new orphan drugs and 20 additional drugs had been proved, compared with the aggregated 34 orphan drugs before its enactment in 1983.[152] Likewise, the more broadly applicable data exclusivity regime established by the Hatch-Waxman Act also spurred the development and testing of new active small-molecule drugs.[153]

In terms of biologics, in the U.S., within the immediate decade prior to the Biologics Price Competition and Innovation Act ("BPCIA", as part of the Patient Protection and Affordable Care Act[154]) that has created the biologics data exclusivity in 2009, only 39 biological products in total were approved by the FDA, as opposed to 85 in aggregate (26 biosimilars inclusive) approved in the following decade, achieving a nearly 1.62-fold increase in the number of biologics approved for marketing.[155] Admittedly, that the soaring number of post-2009 approved biologics could be attributed to reasons other than the establishment of data exclusivity such as science discovery and technology development, but the significant role of the American biologics regulatory data exclusivity regime ought not to be ignored.

The mechanism of incentive is often termed the "Schumpeterian Model".[156] Within this article, this means that the American biologics regulatory data exclusivity promises biologics companies significant income for a specific period after regulatory clearance, allowing them to recoup their investment (including R&D costs) and turn a profit, thereby promoting the development of new biologics. As is well-known, the R&D of new medicines is widely recognized as a great venture, characterized by huge capital investment demand, time-consuming and accompanying high risks, particularly for biologics. According to the latest empirical studies in the U.S., for biologics the median R&D costs were US$ 3 billion (IQR, US$ 1.3 billion – US$ 5.5 billion),[157] the median development times were 12.6 years (IQR, 10.6-15.3 years),[158] the observed success rates of academic drug discovery and

152 Skillington & Solovy, *supra* note 31, at 9, 12–13.

153 *Id.* at 13.

154 Pub. L 111-148, §§ 7001–7003, 124 Stat. 119, 804–23.

155 *See* Beatriz G. Torre & Fernando Alberico, *The Pharmaceutical Industry in 2022: An Analysis of FDA Drug Approvals from the Perspective of Molecules*, 28 MOLECLUES 1038, 1039 (2023). *See also* Yaniv Heled, *The Biologics Price Competition and Innovation Act 10 – A Stocktaking*, 7 TEX. A&M J. PROP. L. 81, 84–85 (2021).

156 Schumpeterian Model can be summarized: R&D investment will automatically increase when the expected financial incentives adequately compensate the risk and costs of R&D. *See* Keith E. Maskus, *The New Globalisation of Intellectual Property Rights: What's New This Time?*, 54 AUSTL. ECON. HIST. REV. 262–84 (2014).

157 Wouters et al., *supra* note 100, at 2104.

158 *Id.* at 2103.

development were 14% (range, 9%-32%) for Phrase I clinical trial, 24% (range, 17%-38%) for Phrase II clinical trial, and 57% (range, 51%-71%) for Phrase III clinical trial.[159] The establishment of the U.S. biologics data exclusivity, especially longer period of exclusivity, has contributed to higher overall revenue, reaching US$ 3.7 billion in median lifetime revenue.[160]

Nonetheless, as the classic old saying– "environment shapes character" – indicates, a well-functioning legal system in one country might work poorly in another country. Some might justifiably inquiry whether the biologics regulatory data protection regime will yield comparable outcomes in China as it has in the U.S. or EU, particularly taking Ms. Diependaele and her co-authors' 2017 assertions into account, of which argues that the regulatory data protection regime (data exclusivity in their study) will not promote innovation as to developing countries.[161]

But can Ms. Diependaele and her co-authors' 2017 assertions really apply to China today? As for this article, it would also be an imprudent movement to directly extrapolate Ms. Diependaele and her co-authors' conclusion to China. In their collaborative article, they equate the patent with the data exclusivity (because both of which can result in market exclusivity and thus produce similar effects), [162] attempting to argue from the standpoint of the patent-innovation relationship that the data exclusivity does not promote innovation. Their principal arguments can be encapsulated as (i) there is no systematical empirical result indicating a positive correlation between patents and innovation in developing countries (measured by patent applications and R&D investment),[163] and (ii) there is little evidence that increasing protection has a positive impact on economic development and innovation in developing countries, which remain net importers of technology.[164]

It must be emphasized that their arguments are highly improbable to reflect China's situation and thus inapplicable. As a starting point, scholars widely recognize that the beneficial impact of intellectual property rights primarily hinges on a nation's innovation capacities,[165]

159 *Id.* at 2103–2104.

160 *Id.* at 2104, 2106.

161 *See* Lisa Diependaele et al., *Raising the Barriers to Access to Medicines in the Developing World – the Relentless Push for Data Exclusivity*, 17 DEV. WORLD BIOETH. 11 (2017).

162 *Id.* at 18 ("[H]owever, because data exclusivity *de facto* confers or lengthens market exclusivity, it must have similar effects to those of patents, hence finding regarding the effects of patent protection on innovation can reveal important trends.").

163 *Id.*

164 *Id.* at 19.

165 *Id.*; *see also* Brent B Allred & Walter Park, *Patent Rights and Innovative Activity: Evidence*

which is often measured by the positive correlation between intellectual property protection and innovation. Fortunately, it can be found that there is a strong positive correlation between patent protection and innovation, in the biologics field, in China since 2012, according to statistical data from the National Bureau of Statistics of China (see Figure 3.,[166] below). This distinct correlation distinguishes China's situation from those of other developing countries, suggesting that it is inappropriate to curtly apply Ms. Diependaele and her co-authors' conclusions to China.

Year	Biologics Patent Application (pieces) "X"	Biologics Firms' R&D Expenditure (10k RMB) "Y"
2012	2,004	478,453
2013	2,421	568,198
2014	3,302	700,644
2015	2,638	799,158
2016	2,970	929,460
2018	3,048	1,092,231
2017	*Data Missing; Exclusive in correlative analysis	
2019	4,044	1,415,669
2020	5,036	1,944,498
2021	6,085	3,049,064
2022	6,706	3,354,224
2023	6,389	3,850,066

$$Pearson\ Correlation\ Coefficient\ (r) = \frac{\sum(x-\bar{x})(y-\bar{y})}{\sqrt{\sum(x-\bar{x})^2 * (y-\bar{y})^2}} = 0.9712$$[167]

Figure 3. Correlation between Patent and R&D Investment (Biologics)

Furthermore, a recent empirical study has revealed that the strengthened patent protection in China, through stringent measures against infringement and counterfeiting, resulted in increased patent counts, augmented R&D investment and benefited risk-taking firms,

from National and Firm-Level Data, 38 J. INT'L BUS. STUD. 878–900 (2007), Yongmin Chen & Thitima Puttitanun, *Intellectual Property Rights and Innovation in Developing Countries*, 78 J. DEV. ECON. 474–93 (2005).

166 *See* Guojia Tongji Ju Shehui Keji & Wenhua Chanye Tongji Si (国家统计局社会科技和文化产业统计司) [DEP'T OF STAT. OF SOC. SCI., TECH. AND CULTURAL INDUS., NAT'L BUREAU OF STATE], Zhongguo Gaojishu Chanye Tongji Nianjian (中国高技术产业统计年鉴) [CHINA HIGH-TECH INDUSTRY STAT. Y.B.] (China Statistics Press, 2013–2024).

167 If $0.8 \leq |r| < 1$, then it indicates there is a strong positive correlation between the variable X and the variable Y.

such as biotech startups and therefore fostered corporate innovation.[168] Likewise, it is reasonable and appropriate to make a comparable analogy that, implementing the biologics regulatory data protection, which serves as another kind of increasing market exclusivity akin to enforcement against the infringement and counterfeiting, can also promote biologics innovation.

More importantly, when focusing on the more fundamental issue in the patent-innovation relationship – the inherent innovation capacity within a country, it can be observed that the Chinese biologics industry has a robust innovation capacity and China is progressively evolving from a technology importer to a technology exporter, especially with regards to biotechnology. [169] Taking Class 1 therapeutical biologics (*i.e.*, therapeutical biologics that are not marketed globally) as an example, China's domestic pharmaceutical companies have exhibited robust innovative capacities with respect to therapeutical biologics over the past three years (see Figure 4., [170] below). Simultaneously, the robust domestic innovation capacities are also evidenced by technological spillovers - it is widely reported and recognized that the out-licensed biological products from China are enriched in younger and more innovative stages, exhibiting a trend from "bring-in" to "go global". [171] These facts suggest that the conclusion reached by Ms. Diependaele and her co-authors is inapplicable to China again.

168 *See* Chen Jianqiang et al. *Cracking Down on the Infringement and Counterfeiting: Intellectual Property Rights and Corporate Innovation in China*, 55 FIN. RSCH. LETTERS 103846, 103851 & 53 (2023).

169 *See generally It's Not Just AI. China's Medicines Are Surprising the World Too*, THE ECONOMIST (Feb. 16, 2025).

170 Statistics of the year 2024, *see* Zhi et al., *Approvals by the China NMPA in 2024*, *supra* note 102; Statistics of the year 2023, *see* Zhi et al., *Approvals by the China NMPA in 2023*, *supra* note 102; Statistics of the year 2022, *see*, 2022 Niandu Yaopin Pingshen Baogao (2022 年度药品评审报告) [2022 ANN. DRUG REV. REP.], Guojia Yaopin Jiandu Guanli Ju (国家药品监督管理局) [Nat'l Med. Prod. Admin.] (Sept. 6, 2023) https://www.nmpa.gov.cn/xxgk/fgwj/gzwj/gzwjyp/20230906163722146.html.

171 Yale Jiang et al., *Trends of Drug Licensing in China: From Bring-in to Go-global*, 210 PHARM. RSCH. 107488, 10751 (2024).

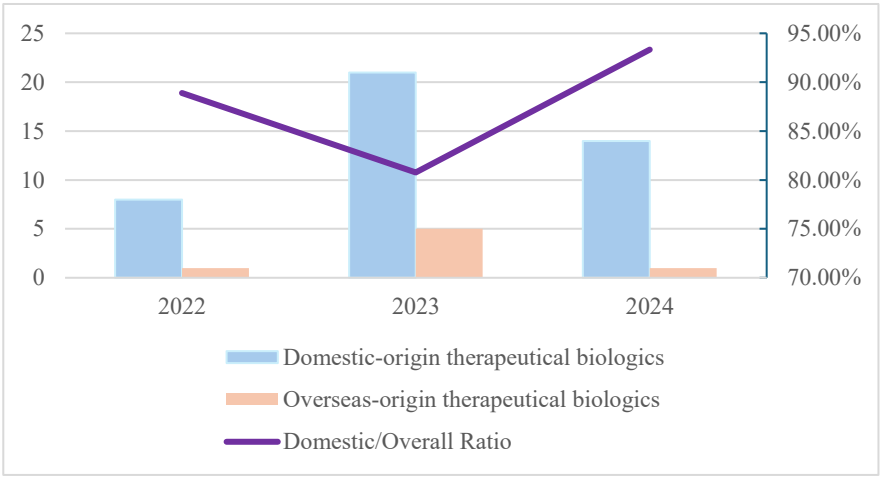

Figure 4. Class 1 Therapeutical Biologics Approved by NMPA (2022-2024)

Based on the aforementioned data and analysis, there are ample justifications to assert that the innovation capacities of China's domestic biotech firms have been sufficient to activate the positive effect of intellectual property rights, thereby further promoting innovation through positive feedback --- increased protection can further promote, rather than diminish, innovation. Observations, by researchers at the University of Chicago, that regulatory data protection alongside traditional intellectual property protection, can offer economic incentives to pharmaceutical enterprises and encourage innovation.[172] These findings are applicable to China, justifying the establishment of such a regulatory data protection regime in China.

2. Biologics Regulatory Data Protection and Public Health: Is Biologics Regulatory Data Protection A Real Barrier To Affordable Biologics?

Biologics regulatory data can bring more than just abundant and better biological products to the market. From a public health standpoint, the growing number of new and better biologics (either in the R&D process or have received marketing authorizations) can lead to the cure of more serious and life-threatening diseases that were previously hard-to-cure or even incurable, which significantly benefits

172 *See generally* George C. Alexander et al., *Enhancing Prescription Drug Innovation and Adoption*, 154 ANNALS INTERNAL MED. 833, 833–37 (2011).

public health.[173]

For example, the COVID-19 mRNA vaccines, one of the many advanced biological products,[174] could consistently prevent long-term COVID symptoms in adults.[175] The CAR-T therapy, another example of frontier biologics, is widely regarded as a major breakthrough in cancer care since 2017.[176] Apart from cancer treatment, CAR-T therapy is also being explored for the treatment of various pathological conditions such as autoimmune diseases, fibrotic diseases, infectious diseases etc.[177] All of these high-end biologics demonstrate how the biologics innovation is profoundly impacting and transforming the global public health landscape.

Some might counterargue that, artificially conferring biologics regulatory data protection will make it extremely hard for ordinary people to afford medical costs and does not yield substantial advantages for public health because it effectively creates a monopoly delaying biosimilars' market entry for a certain duration and therefore maintaining elevated medicine prices. The economic principles underpinning the foregoing argument are clear: assuming stable demand, prices will decline as supply increases. Specifically, market competition introduced by biosimilars will lower the price of biologics for identical/similar indications, while biological regulatory data protection fundamentally eliminates this competition from the ground up.

In response to the foregoing argument, it is crucial to clarify that the "race/competition" between reference biologics and biosimilars occurs in two stages: (i) at Stage-I, only the reference biologics are available in the market[178] because the data protection regime often denies follow-on biosimilars, (ii) at Stage-II, reference biologics competes with biosimilar(s) since the expiry of patent or expiry of

173 *See* Olasupo Owoeye & Oluwabusayo Owoeye, *Biologics and Public Health: Prospects and Challenges*, 26 J. LAW MED. 170, 170 (2018). *See also* WHO, *Biologics: Impact*, https://www.who.int/health-topics/biologicals#tab=
tab_2 (last visited June 8, 2025).

174 *See* Sarfaraz K. Niazi, *RNA Therapeutics: A Healthcare Paradigm Shift*, 11 BIOMEDICINES 1275, 1283 (2023) ("mRNA products are classified as biological drugs, despite being synthetic products.").

175 Nhung TH Trinh, *Effectiveness of COVID-19 Vaccines to Prevent Long COVID: Data from Norway*, 12 LANCET 225, 225 (2024).

176 *See generally*, Aroshi Mitra et al., *From Bench to Beside: The History and Progress of CAR T Cell Therapy*, 14 FRONT IN IMMUNOLOGY 1 (2023).

177 *Id.* at 10.

178 Unlike the "Exclusivity Model", the "Anti-unfair-use Model" doesn't bar biosimilars into the market so long as the generic companies can submit their own test data and obtain regulatory approval. Therefore, it is theoretically possible to see biosimilars in the market at this stage under the "Anti-unfair-use Model".

regulatory data protection, whichever is later.

It is unnecessary to spill much more ink on justifying the existence of a biologics regulatory data regime during the Stage-1 period, as thoroughly addressed in detail in Section V.B.1 of this article: focusing on affordability before increasing availability is putting the cart before the horse, that is, without strong incentives provided by this regime, the public cannot realistically access benefits offered by more innovative biologics targeting at multiple indications.

Stage-II warrants more in-depth analysis and discussion. The party that is opposed to or skeptical of the regulatory data protection regime contends that reference biologics "unfairly compete" with biosimilars (at Stage-II) and attributes their perceived "unfortunate" status to the data protection regime. They first rely on research to argue that it has led to the relevant party's dependence on reference drugs because of the first-mover advantage gained by reference drugs when such drugs enter the market first. For example, it is reported that many physicians (and therefore also patients) remain reluctant to use biosimilars, especially when doing so involves switching patients from the reference product to a biosimilar.[179] Secondly, it has been found that biosimilars have historically captured just 25% of the biologic market within 2 years of first biosimilar entry, with an average price reduction on biologics reference products of less than 10% in America.[180] These studies support their arguments that (i) the drug-patient dependence will be reduced and the price will be significantly lowered should follow-on product manufactures were allowed to "piggyback" on earlier approvals of reference product and make their own version copycat versions.[181]

It is important to acknowledge that the empirical data from the U.S. does not accurately represent reality. The prerequisite for price decrease resulting from competition between reference biologics and biosimilars is twofold: (i) the biosimilars being able to enter the market, and (ii) the reference biologics and biosimilars being substitutes to each other in an economic sense.[182] Subject to drug regulations, the economic-sense "substitution" largely depends on the "interchangeability" allowed by regulations, where the pharmaceutical-contented "interchangeability" means that a

179 Liese Barbier & Arnold G. Vulto, *Interchangeability of Biosimilars: Overcoming the Final Hurdles*, 81 DRUGS 1897, 1898 (2021). *See also* Daniel K Mroczek et al., *Obstacles to Biosimilar Acceptance and Uptake in Oncology: A Review*, 10 J. AM. MED. ASS'N 966 (2024).

180 Wouters et al., *supra* note 100, at 2105–6.

181 Heled, *supra* note 155, at 87–88.

182 *See FDA Report: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices*, FDA (Oct. 17, 2024), https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices. *See also* Heled, *supra* note 155, at 96.

biosimilar with an "interchangeable" designation can be substituted for its reference medicine at the pharmacy, without additional approvals from the prescribing physician.[183] As Mr. Heled observed in his 2021 article, U.S. federal law does not allow the FDA to grant "automatic substitution, *i.e.*, interchangeability" to biosimilars, resulting that competition between reference biologics and non-interchangeable biosimilars has not and is unlikely to result in significant price competition in the U.S.[184]

A step further, under the premise of solving the problem of interchangeability, can biologics prices really be reduced due to market competition between reference biologics and biosimilars? Mr. Heled asserted in his article that the price competition effect would ensue in the U.S. should the FDA recognize the interchangeability of reference biologics and biosimilars.[185] Nevertheless, this article argues that the biologics price reduction extrapolated by Mr. Heled will not be so easily achieved through simply removing the bar against interchangeability. It is noted that the year following the publication of Mr. Heled's 2021 article, an empirical study conducted in Finland suggests that, given that Finnish Medicines Agency permitted the interchangeability of biosimilars since May 22, 2015,[186] the reduction in prices of reference biologics was primarily ascribed to the Finnish public reimbursement legislations, rather than the genuine price competition between the biosimilars and the reference biologics.[187]

This Finnish study is enlightening and possesses considerable

183 *5 Things Worth Knowing About Biosimilars and Interchangeability.*, PFIZER (Dec. 12, 2023), https://www.pfizer.com/news/articles/5_things_worth_knowing_about_biosimilars_and_interchangeability.

184 Heled, *supra* note 155, at 96.

185 *Id.* at 95–96 ("[B]ut the most crucial delay has been in the implementation of BCIPA's most important part: the creation of a pathway for approval of *interchangeable* biosimilars. …. Yet it took the FDA more than nine years after the enactment of BPCIA to issue its guidance on how the FDA intends to evaluate interchangeability of follow-on biologics."). *See also* Heled, *supra* note 155, at 96 n.52. ("[H]owever, without interchangeability such price drops are highly unlikely in the United States, which – unlike European countries (and virtually all other countries) – has no means for controlling the price of pharmaceuticals and relies exclusively on competition to lower the cost of biologics in hopes that market mechanisms would, eventually, result in increased access.").

186 *See Interchangeability of Biosimilars – Position of Finnish Medicines Agency Fimea*, FINNISH MED. AGENCY, (May 22, 2015), https://fimea.fi/documents/147152901/159459777/29197_Biosimilaarien_vaihtokelpoisuus_EN.pdf/611bf7a4-2135-4364-aa50-74ab8d412495?t=1707134445259.

187 *See* Sanna V. Luukkanen et al., *The Price and Market Share Evolution of the Original Biologics and Their Biosimilars in Finland*, 36(4) BIODRUGS 537, 546 (2022) ("[T]he market entry of biosimilars induced a reduction in the prices of the reference products in outpatients care in Finland. However, the prices of the reference products decreased mainly because of the public reimbursement legislation. Therefore, biosimilars did not create genuine price competition between the biosimilar and the reference product.").

guiding significance. It acquits the blame on the biologics regulatory data protection, proving that there is no substantial causal link between price reduction and the purported market competition between reference biologics and biosimilars. As for China's practice, this might also suggest that if China can implement public reimbursement regulations similar to the Finnish's, biologics data protection will not be a substantial obstacle to affordable biologics nor constitute a barrier to public health at large.

C. Alienation with international practice

Finally, alongside the need for a biologics regulatory data protection regime from the viewpoints of intellectual property and drug laws, China's international legal practice necessitates the establishment of its own biologics regulatory data protection regime.

On June 28, 2023, the Standing Committee of the National People's Congress of the People's Republic of China enacted the Law on Foreign Relations, effective on July 1, 2023. Article 30 of the Law on Foreign Relations, transforming Article 26 of the VCLT[188] into the PRC domestic law, mandates that the Chinese government must honor its obligations imposed by effective international treaties in good faith, *provided that* these international treaties do not conflict with its Constitution.[189]

Currently, two effective international treaties obligate the Chinese government to protect biologics regulatory data, namely, (1) the China-Switzerland FTA (Article 11.11, § 2) and (2) the Economic and Trade Agreement Between the Government of the People's Republic of China and the Government of the United States of American (Section C, preamble[190]). Besides, the Chinese government is not exempted from treaty obligations due to the Article 30 "Constitution contradiction exception" because the biologics regulatory data protection regime fosters the development of novel biologics, ultimately benefiting public health, as discussed *supra* Section IV.B.

188 VCLT, art. 26 ("[E]very treaty in force is binding upon the parties to it and must be performed by them in good faith.")

189 Law on Foreign Relations, art. 30.

190 OFF. OF THE U.S. TRADE REPRESENTATIVE & U.S. DEP'T OF TREASURY, *Economic And Trade Agreement, China-U.S.* , OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE (Jan. 15, 2020), § C, https://ustr.gov/sites/default/files/files/agreements/phase%20one%20agreement/Economic_And_Trade_Agreement_Between_The_United_States_And_China_Text.pdf. ("…, [T]he Parties shall provide for effective protection and enforcement of pharmaceutical-related intellectual property rights, including patents and undisclosed test or other data or other data submitted as a condition of marketing approval."). Despite the China-U.S. Economic and Trade Agreement mandates so, this article will discuss China-Switzerland FTA only.

Consequently, establishing the biologics regulatory data protection regime aligns with the principles of "encouragement of modern pharmaceuticals" and "protection of people's health" as stated by Article 21 of the PRC Constitution.[191]

Therefore, from a normative standpoint, there is no room for the Chinese government not to protect the biologics regulatory data, as mandated by Article 11.11 §2 of the China-Switzerland FTA. Regrettably, the State Council of China removed the drafting provision reading that "[T]he State protects the undisclosed test and other data of drugs approved for marketing" while retaining the original phrase "drugs … which contains new chemical entities" in the effective *2024 Regulations for the Implementation of the Drug Administration Law.* This action indicates that the Chinese regulatory data protection regime is still limited to new chemical entity drugs only, precluding first-in-class biologics.

The Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) should also be pointed out as a minor issue in this context. Article 11.51 of CPTPP requires its Member States to protect the biologics regulatory data for a duration of 8 years from the date of first marketing approval. Although China has only applied for membership in the CPTPP and Article 11.51 of CPTPP is currently suspended, the initiative to establish China's own its own biologics regulatory data remains significant as China aims to create a more inclusive and interconnected global trading system that benefits all participants.[192]

VI. CONCLUSION

Art.39.3 of the TRIPS Agreement, established thirty years ago, offers pharmaceutical test data protection on a global basis. But now, the pharmaceutical industry has evolved significantly since the 1990s — 21st century advanced biologics offers greater benefits than chemical drugs in serving the public good: treating a wide range of medical illnesses and conditions for which there used to be no alternative treatment. Therefore, stakeholders have become apprehensive regarding whether advancements in modern biotechnology developments have crossed beyond the protected scope by Art.39.3.

191 *See* XIANFA art. 21, § 1 (2018) (China) ("The State develops medical and health services, develops modern pharmaceuticals and traditional Chinese medicine […] and protects people's health.").

192 *China to Speed Up Accession to CPTPP*, ST. COUNCIL, (Mar. 22, 2024, 09:25 AM), https://english.www.gov.cn/news/202403/22/content_WS65fcddf2c6d0868f4e8e555c.html.

Unfortunately, neither the TRIPS Agreement itself nor its authoritative interpreter have clarified whether the regulatory data of novel and high-end biologics are within the scope of Art.39.3, leading to two opposing views among scholars and practitioners.

This article first elucidates the regulatory essence of the subject under Art.39.3 that the undisclosed data/regulatory data refers to clinical test data which are generated during the preclinical and clinical trials of a drug, and are utilized to substantiate the drug's safety, efficacy and quality in its application for marketing authorization. The article then takes the Hatch-Waxman Act as a classic example to illustrate why both brand-name and generic pharmaceutical companies value the regulatory data so much: the generic drug approval pathway is what makes the regulatory data significant for both parties, for brand-name companies to reign supreme in the market position and also for generic companies to share a slice of the market pie.

The Hatch-Waxman Act further bridges this article to the drafting history of Article 39.3 of the TRIPS Agreement. Adequate drafting and negotiation materials of the TRIPS Agreement have been examined to investigate a genuine and rational intention of Member States with respect to the subject of Art.39.3. This article begins with the most representative minority view by Mr. Solovy, explaining why Mr. Solovy's interpretation is incorrect considering the context of the pharmaceutical industry and the Art.39.3 subject drafting history, in accordance with the VCLT and interpretation rules of the WTO panels and Appellate Body. This article concludes that Art.39.3 of the TRIPS Agreement does not offer protection for biologics regulatory data.

Following the conclusion towards the scope of Art.39.3, this article proceeds to examine whether China - since its accession to the WTO in 2001 and its transformation of Art.39.3 in 2002 - protects biologics regulatory data. Regrettably, this article finds that despite China's persistent attempts to protect biologics regulatory data, such data remains unprotected.

Recognizing the vacancy in terms of biologics regulatory data protection in China, this article seeks to present legal arguments on advocating for establishing a biologics regulatory data protection regime from three perspectives. First, from the *de lege lata* perspective, the patent law is far from ideal for protecting brand name pharmaceutical companies' interest in their first-in-class biologics, where data protection could effectively address the shortcomings of patent protection. Second, this article relies on empirical studies in the U.S. to elucidate how a *de lege ferenda* biologics regulatory data protection regime could incentivize novel biologics innovation and benefit public health. Additionally, this article references an empirical

study from Finland to argue against attributing the obstruction of affordable biological products to the biologics regulatory data protection regime. Finally, from the *lex ferenda* perspective, this article argues that China has a legal imperative to establish such a regime to fulfill its international law obligation, *inter alia*, the obligation imposed by Article 11.11 §2 of China-Switzerland FTA, in good faith.

In conclusion, following China's accession to the WTO in 2001 and subsequent incorporation of Art.39.3 into its domestic law in 2002, China has probably followed the stance of Art.39.3 on not granting regulatory data protection to biologics over the ensuing 23 years. However, biotechnological advancements over the past thirty years have crossed far beyond the scope of Art.39.3 and its Chinese equivalent, necessitating the implementation of regulatory data protection for biologics. This article explains on three most pivotal aspects of supporting the establishment of a Chinese biologics regulatory data regime, aiming to provide valuable references and recommendations should China authorities choose to establish such a regulatory data protection regime for biologics.

This article discusses the necessity of establishing the Chinese biologics regulatory data protection regime in principle, echoing China's ambitious biotech goals outlined in *Made in China 2025*.[193] Nonetheless, this article also realizes that more detailed regulations of the biologics regulatory data protection regime, such as the protection model (U.S.-EU data exclusivity model or Art.39.3 anti-unfair-use model) and duration (American 12 years, or European 8+1+2 years, or an alternative duration), require more empirical research in light of China's actual situations. Therefore, this article also calls for more in-depth empirical research and legal analysis to address the above details and related regimes, such as the connections between the biologics regulatory data protection regime and patent challenge system, and between the medical reimbursement reform system.

193 *See* Guowuyuan Guanyu Yinfa Zhongguo Zhizao 2025 Tongzhi (国务院关于印发《中国制造 2025》的通知) [Notice of the St. Council on Issuing "Made in China 2025"], St. Council (May 19, 2015) ("Biomedicines and high-performance medical devices" is one of ten key areas in *Made in China 2025*.).