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Addressing Barriers to Accessing Monoclonal Antibodies (mAbs) in Developing Countries: Challenges and Potential Solutions

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ABSTRACT

Monoclonal antibodies (mAbs) have revolutionized treatment in oncology, autoimmune disorders, and infectious diseases due to their high specificity and efficacy. However, access to mAbs in developing countries remains severely limited due to high costs, market concentration in high-income regions, regulatory hurdles, and intellectual property barriers. Despite the potential of biosimilars to enhance affordability, their availability remains restricted due to expensive development processes, patent thickets, and complex regulatory requirements. The dominance of multinational pharmaceutical companies in the market further restricts competition, delaying biosimilar approvals and preventing price reductions. Additionally, regulatory agencies in developing countries often lack the resources to expedite biosimilar approvals, further exacerbating delays in access.

Policy interventions such as improved regulatory harmonization, stricter patent examination guidelines, and expanded public investment in mAb production are necessary to address these barriers. The adoption of the revised 2022 WHO Similar Biotherapeutic Products (SBP) Guidelines could streamline biosimilar approval by reducing unnecessary comparative clinical trials. Moreover, technology transfer initiatives and market-shaping incentives, including compulsory licensing, could help lower costs and accelerate the availability of mAbs in underserved regions.

By implementing these strategies, developing countries can bridge the access gap, ensuring that lifesaving mAb therapies reach the patients who need them most. A coordinated global effort involving policymakers, regulators, and industry stakeholders is essential to establishing a sustainable and equitable mAb supply chain.

Les anticorps monoclonaux (mAbs) ont révolutionné les traitements en oncologie, dans le domaine des maladies auto-immunes et des maladies infectieuses grâce à leur grande spécificité et à leur efficacité. Cependant, l'accès aux anticorps monoclonaux dans les pays en développement reste très limité en raison de leur coût élevé, d'une concentration du marché dans les régions à revenu élevé, d'obstacles réglementaires et de barrières liées à la propriété intellectuelle. Malgré le potentiel des biosimilaires pour rendre ces traitements plus abordables, leur disponibilité reste restreinte en raison de processus de développement coûteux, d'un enchevêtrement de brevets et d'exigences réglementaires complexes. La domination des multinationales pharmaceutiques sur le marché restreint encore davantage la concurrence, retardant les autorisations de mise sur le marché des biosimilaires et empêchant toute baisse des prix. De plus, les agences de réglementation des pays en développement manquent souvent les ressources nécessaires pour accélérer les autorisations de mise sur le marché des biosimilaires, ce qui aggrave encore les retards d'accès.

Des interventions politiques telles qu'une meilleure harmonisation réglementaire, des directives plus strictes en matière d'examen des brevets et un investissement public accru dans la production d'anticorps monoclonaux sont nécessaires pour surmonter ces obstacles. L'adoption des Lignes directrices révisées de l'OMS de 2022 sur les produits biothérapeutiques similaires (SBP) pourrait rationaliser l'autorisation des biosimilaires en réduisant les essais cliniques comparatifs inutiles. De plus, des initiatives de transfert de technologie et des mesures incitatives visant à façonner le marché, y compris les licences obligatoires, pourraient contribuer à réduire les coûts et à accélérer la mise à disposition des anticorps monoclonaux dans les régions mal desservies.

En mettant en œuvre ces stratégies, les pays en développement peuvent combler l'écart d'accès, garantissant ainsi que les traitements par anticorps monoclonaux vitaux parviennent

aux patients qui en ont le plus besoin. Un effort mondial coordonné impliquant les décideurs politiques, les régulateurs et les acteurs du secteur est essentiel pour établir une chaîne d'approvisionnement en anticorps monoclonaux durable et équitable.

Los anticuerpos monoclonales (mAb) han revolucionado el tratamiento de la oncología, las enfermedades autoinmunes y las enfermedades infecciosas gracias a su alta especificidad y eficacia. Sin embargo, el acceso a los mAb en los países en desarrollo sigue siendo muy limitado debido a los elevados costes, la concentración del mercado en las regiones de altos ingresos, los obstáculos normativos y las barreras relacionadas con la propiedad intelectual. A pesar del potencial de los biosimilares para mejorar la asequibilidad, su disponibilidad sigue siendo limitada debido a los costosos procesos de desarrollo, la maraña de patentes y los complejos requisitos normativos. El concentración de empresas farmacéuticas multinacionales en el mercado restringe aún más la competencia, lo que retrasa las aprobaciones de biosimilares e impide la reducción de precios. Además, las agencias reguladoras de los países en desarrollo suelen carecer de los recursos necesarios para agilizar las aprobaciones de biosimilares, lo que agrava aún más los retrasos en el acceso.

Para abordar estas barreras son necesarias intervenciones políticas como una mayor armonización regulatoria, directrices más estrictas para el examen de patentes y una mayor inversión pública en la producción de mAb. La adopción de las Directrices revisadas de la OMS de 2022 sobre productos bioterapéuticos similares (SBP) podría agilizar la aprobación de los biosimilares al reducir los ensayos clínicos comparativos innecesarios. Además, las iniciativas de transferencia de tecnología y los incentivos para la configuración del mercado, incluida la concesión de licencias obligatorias, podrían ayudar a reducir los costes y acelerar la disponibilidad de mAb en regiones desatendidas.

Mediante la aplicación de estas estrategias, los países en desarrollo pueden reducir la brecha de acceso y garantizar que los tratamientos con anticuerpos monoclonales, que salvan vidas, lleguen a los pacientes que más los necesitan. Es esencial un esfuerzo global coordinado en el que participen responsables políticos, organismos reguladores y partes interesadas del sector para establecer una cadena de suministro de anticuerpos monoclonales sostenible y equitativa.

单克隆抗体（mAbs）凭借其高度的特异性和疗效，已在肿瘤、自身免疫性疾病和感染性疾病的治疗领域引发革命性变革。然而，由于成本高昂、市场向高收入地区集中、监管障碍以及知识产权壁垒，发展中国家获得单克隆抗体的机会仍然极为有限。尽管生物类似药有望提高可负担性，但由于开发过程昂贵、专利丛林现象以及复杂的监管要求，其供应仍然受到限制。跨国制药公司在市场上的主导地位进一步限制了竞争，延缓了生物类似药的审批进程，并阻碍了价格下调。此外，发展中国家的监管机构往往缺乏加快生物类似药审批所需的资源，这进一步加剧了患者获得治疗的延迟。

为消除这些障碍，必须采取政策干预措施，例如加强监管协调、制定更严格的专利审查指南，以及扩大对单克隆抗体生产的公共投资。采用修订后的《2022年世界卫生组织类似生物治疗产品（SBP）指南》可通过减少不必要的比较性临床试验来简化生物类似药的审批流程。此外，技术转让举措以及包括强制许可在内的市场引导性激励措施，有助于降低成本并加速单克隆抗体在医疗资源匮乏地区的供应。

通过实施这些策略，发展中国家能够弥合可及性差距，确保挽救生命的单克隆抗体疗法能够惠及最需要它们的患者。**要建立一个可持**续且公平的单克隆抗体供应链，必须由政策制定者、监管机构和行业利益相关方共同参与，开展协调一致的全球行动。

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I. INTRODUCTION

Monoclonal antibodies (mAbs) are a class of biologic drugs that are made of big molecules of laboratory-made proteins designed to bind to a specific epitope of an antigen. They are produced from a single clone of a specific B cell (a type of white blood cell), allowing these antibodies to target a specific pathogen or disease. Monoclonal antibodies offer high specificity, consistency, scalability, lower contamination risk, greater precision in diagnosis and therapy,[1] longer shelf life than alternative treatments such as polyclonal antibodies.[2] Due to these features, mAbs have transformed treatment paradigms in oncology,[3] autoimmune disorders, and infectious diseases.[4] Despite their potential to reduce treatment costs, mAbs remain largely concentrated in developed country markets, which account for over 90 percent of global sales. In particular, mAbs are not widely available in developing countries, primarily due to prohibitive costs, regulatory challenges, and limited market size.[5] The disparity in access is particularly stark for diseases like Ebola and respiratory syncytial virus (RSV), where mAbs have been developed but remain inaccessible to the populations most affected by these conditions.[6]

This paper examines key obstacles to mAb access in developing countries, including market concentration, regulatory barriers, and intellectual property restrictions. It also explores technological and policy innovations that could improve accessibility and affordability. The paper concludes with integrated recommendations to create a sustainable and equitable supply of mAbs in developing countries.

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[1] See generally, Cleveland Clinic, Monoclonal Antibodies. Available from https://my.clevelandclinic.org/health/treatments/22246-monoclonal-antibodies.

[2] Antibodies are proteins made by the immune system to fight harmful substances (**antigens**) like viruses and bacteria. They recognize specific parts of antigens called **epitopes**. **Polyclonal antibodies** are produced by multiple immune cells and can bind to different epitopes, making them quick and easy to produce but less specific. They are extracted from human or animal blood and are used in serum or plasma-based therapies to treat some infectious diseases (e.g., rabies, diphtheria, tetanus, etc.), immune disorders (e.g., Guillain-Barre Syndrome, Kawasaki disease, etc.) and venom and toxin neutralization (e.g., snake bites, scorpion stings, etc.). **Monoclonal antibodies** come from a single cell type, targeting only one epitope, making them more precise but harder to produce.

[3] David Zahavi and Louis Weiner, "Antibodies in Cancer Therapy", *Antibodies (Basel)*, vol. 9, no. 3 (July 2020). Available from https://pmc.ncbi.nlm.nih.gov/articles/PMC7551545/#:~:text=As%20a%20result%20of%20these,effector%20responses%20against%20the%20tumor.

[4] See Wellcome IAVI, "Monoclonal antibodies: a new era in the prevention and treatment of disease." Available from https://cms.wellcome.org/sites/default/files/monoclonal-antibodies-supplement-new-era-disease-treatment-prevention.pdf.

[5] Malhotra, S., et al. (2024). Novel Approaches to Enable Equitable Access to Monoclonal Antibodies in Low- and Middle-Income Countries. *PLOS Global Public Health*, 4(7),

[6] See Medecins Sans Frontieres Access Campaign, Ensuring Access to New Treatments for Ebola Virus Disease, May 2023. Available from https://msfaccess.org/sites/default/files/2023-05/MSFAC_EbolaReport_May2023_Final_ENG.pdf. In 2018, 99% of Synagis sales—a drug used to prevent RSV—occurred in the U.S. and Europe, even though 99% of RSV-related deaths took place in developing countries. See Wellcome IAVI, "Expanding access to monoclonal antibody-based products: A global call to action," p.17. Available from https://www.iavi.org/fact-sheet/expanding-access-to-monoclonal-antibody-based-products-a-global-call-to-action-2020/.

II. MARKET CONCENTRATION AND PRICING DISPARITIES

The global mAb market is heavily concentrated in high-income countries, with over 90 percent of sales occurring in the United States (US) and Europe.[7] Biosimilar mAbs, which are highly similar to originator mAbs in terms of structure and function, offer a potential solution to the accessibility challenges. However, access to biosimilars is generally limited in developing countries.

Biosimilars are cheaper than their originator counterparts, in most cases up to about 50 percent.[8] Quality assured biosimilars provide safe and more affordable alternatives to originator biologic medicines.[9] Biosimilars have been recognized by the World Health Organization (WHO) as key drivers for enhancing global access to essential biological medicines. However, the global biosimilar market is also highly concentrated in developed countries even though developing countries like India, China, Iran and Argentina are the leading biosimilar manufacturing countries.[10]

Nevertheless, the growth opportunities in the biosimilars market are significant and these opportunities are primarily expected to be driven by emerging markets in developing countries.[11] In view of this opportunity, many originator multinational biologics companies are launching biosimilars to offset revenue losses from patent expiration and compete in the biosimilars market. For example, the multinational company Pfizer, which is the originator of a number of mAb products (e.g., avelumab), has also produced biosimilars of Roche's Herceptin (trastuzumab) which is supplied in the European market under the brand name "Trazimera". In 2023, Abbott Laboratories announced plans to commercialize several mAb biosimilars in key emerging markets across Latin America, Southeast Asia, the Middle East and Africa, in a collaboration with mAbxcience.[12] Treatments with mAbs continue to be significantly delayed in developing countries as pharmaceutical originator companies continue to prioritize more profitable markets in developed countries, resulting in many mAbs not being registered or filed for approval in developing countries.[13]

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[7] See Ying Chen et al., "An inflection point for biosimilars", McKinsey & Company, 7 June 2021. Available from https://www.mckinsey.com/industries/life-sciences/our-insights/an-inflection-point-for-biosimilars.

[8] Wayne Winegarden, "Biosimilars Often Reduce prices by 50 Percent or More", Centre for Medical Economics and Innovation, 1 October 2024. Available from https://medecon.org/biosimilars-often-reduce-prices-by-50-percent-or-more/.

[9] WHO, "Biosimilars: expanding access to essential biologic therapies", 13 February 2025. Available from https://www.who.int/news/item/13-02-2025-biosimilars--expanding-access-to-essential-biologic-therapies.

[10] Kevin Klein, et al., "The Global Landscape of Manufacturers of Follow-on Biologics: An Overview of Five Major Biosimilar Markets and 15 Countries", *BioDrugs*, vol. 37 (2023), pp. 235-45. Available from https://link.springer.com/article/10.1007/s40259-022-00568-0.

[11] Deloitte, Winning with biosimilars: opportunities in global markets, 2015. Available from https://www2.deloitte.com/content/dam/Deloitte/us/Documents/life-sciences-health-care/us-lshc-biosimilars-whitepaper-final.pdf.

[12] Abbott, Abbot Broadens Access to Cutting-Edge Biosimilars in Key Emerging Markets, Press Release, 20 September 2023. Available from https://abbott.mediaroom.com/2023-09-20-Abbott-Broadens-Access-to-Cutting-Edge-Biosimilars-in-Key-Emerging-Markets.

[13] Wellcome-IAVI, "Expanding access to monoclonal-antibody based products: a global call to action", p. 5. Available from https://cms.wellcome.org/sites/default/files/expanding-access-to-monoclonal-antibody-based-products.pdf.

III. HIGH COSTS AND MANUFACTURING COMPLEXITIES

Monoclonal antibodies are among the most expensive therapeutic options, with annual treatment costs in the US ranging from $15,000 to $200,000 per patient. In developing countries, their high prices often makes them unaffordable, with limited biosimilars competition offering only a modest 10–35 percent reduction compared to original products. By contrast, small-molecule generic drugs can be sold at prices more than 90 percent lower than their originator equivalents.[14]

The complexity of biologic drugs stems from their sensitivity to both the starting materials and the manufacturing process. One approach of producing mAbs is the traditional hybridoma technology, which involves fusing immune cells with myeloma cells to generate hybridomas capable of secreting antibodies. Alternatively, recombinant DNA technology allows for the genetic engineering of host cells to produce optimized antibodies. Since mAbs originate from living cells, even minor variations in cell lines or production conditions can significantly alter the final product. Consequently, biosimilar manufacturers must use starting materials and implement processes that ensure similarity with the originator product in terms of potency, safety, and efficacy.

The difficulty in replicating biologics contributes to the challenges of biosimilar manufacturing. Without direct access to the originator's proprietary production methods, biosimilar manufacturers must develop their own processes, which require research and development investments, and which may introduce structural differences with the originator product if not properly conducted. This extensive process and, in addition, the need to carry out tests as required by the regulatory authorities drives up development costs, which range from $75 million to $250 million per molecule—approximately ten times higher than for small-molecule generics.[15]

Another major challenge to expanding access is the cost of production, which is also significantly greater than that of small-molecule drugs.[16] The production of mAbs requires advanced mammalian cell cultures, rigorous purification and quality control, specialized storage, all of which contribute to their high cost. The cost of goods sold (COGS) has traditionally ranged from $50 to $100 per gram, driven by the expense of bioreactors, skilled labour, and raw materials.[17]

Although high development and production costs have led to the assumption that biosimilars will always result in only modest savings, real-world cases suggest otherwise. For example, the United Kingdom's National Health Service (NHS) projected annual savings of up to £300 million following the introduction of biosimilar versions of adalimumab, reducing expenditures

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[14] Ibid.

[15] Bruno Calo-Fernandez and Juan Leonardo Martinez-Hurtado, "Biosimilars: Company Strategies to Capture Value from the Biologics Market", *Pharmaceuticals*, vol. 5 (No. 12), 2012, pp. 1393-1408. Available from https://doi.org/10.3390/ph5121393.

[16] MAbs are too large to be made using simple chemical methods, and they require specific processes like glycosylation (attachment of carbohydrate to protein) and folding (polypeptide chains in a protein molecule need to be folded in the desired shape to perform a desired function) to function properly. This means that simpler organisms can't be used to produce them. Instead, mAbs need to be made in mammalian cells, which can handle these complex tasks. However, producing mAbs in mammalian cells is complicated and costly because the cells grow slowly and produce less. The most common cells used are Chinese hamster ovary (CHO) cells. The genes for the mAb are added to these cells, which then secrete the antibodies into a liquid that is later purified. Although effective, this process is slow, requires a lot of steps, and increases the cost of producing mAbs, making them an expensive treatment option.

[17] See, e.g., Singh, R. et.al. Recent Advances in the Development of Monoclonal Antibodies and Next Generation Antibodies. *Immunohorizons* https://pmc.ncbi.nlm.nih.gov/articles/PMC10759153/#s24.

from the previous £400 million through competitive negotiations.[18] Additionally, some studies argue that biosimilar development costs may be overestimated. Advances in analytical techniques have improved the ability to establish biosimilar equivalence, potentially eliminating the need for costly clinical efficacy studies. Such regulatory streamlining could further reduce development expenses and accelerate the availability of more affordable treatments worldwide. Some have also contended that multinational pharmaceutical companies that enter the biosimilars market to offset the commercial loss arising from expiry of patent monopolies on blockbuster originator biologic drugs have a stake in keeping the prices of biosimilars comparatively high.[19]

In addition, process optimizations and technological advancements have begun to lower the production costs. Improvements in product design have enhanced mAb potency and extended their half-life, while innovations in large-scale production have enabled manufacturers to achieve COGS below $50 per gram in highly optimized settings.[20]

Despite significant advancements in manufacturing technologies that have greatly reduced the production costs of mAbs over the past three decades, these savings have not consistently resulted in lower prices for patients. Consequently, the financial burden on patients continues to be substantial, limiting accessibility to these therapies, especially in developing countries.[21] However, some biosimilar companies have been able to reduce the price of some of their mAbs products to a significant extent. In India, for example, Glenmark reduced the cost of its 440mg vial of trastuzumab. Even with price reductions, affordability remains a challenge, as even the lowered prices are still out of reach for many patients.

Some developing countries, such as Argentina, Brazil, India, and Egypt, have expanded their mAb manufacturing capacities. To expand biosimilars production in developing countries and enhance affordability, policy interventions such as market-shaping incentives, price negotiations, and pooled procurement mechanisms must be prioritized. Further, regulatory simplifications that allow for easier biosimilar approvals can accelerate cost reductions.

[18] "NHS to save £300 million on cost of most expensive drug", The Independent, 25 November 2018. Available from https://www.the-independent.com/news/health/nhs-save-adalimumab-300-million-simon-stevens-nurses-a8651516.html.
[19] Amit Sengupta, *Biological Drugs: Challenges to Access (*Third World Network, Penang, 2018), p.16.
[20] Malhotra, S., et al., *supra* note 5.
[21] Bill & Melinda Gates Foundation, Innovations for Exceptionally Low-Cost Monoclonal Antibody (mAb) Manufacturing. Available from https://gcgh.grandchallenges.org/challenge/innovations-exceptionally-low-cost-monoclonal-antibody-mab-manufacturing.

IV. INTELLECTUAL PROPERTY BARRIERS

IV.1 Patents

Increased availability and affordability of mAbs are critical for increasing access in developing countries. This can be substantially facilitated, with the limitations mentioned above, by ensuring the availability of biosimilar mAbs. However, biosimilars are most likely to seek market entry only when the patent of the originator company expires. In this context, the existence of patents covering particular mAbs become a critical factor. Such patents could also impact access to treatment during public health emergencies, as seen in the recent COVID-19 pandemic.[22]

Originator biologics manufacturers often build dense "patent thickets" by filing numerous patents on various aspects of their biologics—such as manufacturing processes, formulations, dosing regimens, and even minor modifications—which extend market exclusivity and delay biosimilar competition. This fragmented patent landscape creates significant legal and financial hurdles for biosimilar developers, increasing development costs and litigation risks while postponing market entry and maintaining high drug prices.[23]

A recent empirical study has highlighted that manufacturing "platform patents" have become a significant factor delaying biosimilar competition.[24] Unlike product-specific patents, these broadly applicable patents cover standardized manufacturing processes—such as cell-line development, protein purification, and formulation—that can be used across multiple biologic products.[25] Originator companies have increasingly relied on such platform patents to extend their market exclusivity.[26] The study, which examined patent portfolios of nine major biologics manufacturers in United States, found that originator firms hold extensive numbers of these platform patents relative to their approved biologicals, suggesting a deliberate strategy to deter biosimilar entry. Since these patents are often filed after marketing authorization and are not tied to the original manufacturing process, they generate substantial legal uncertainty and increase litigation under the Biologics Price Competition and Innovation Act (BPCIA). The authors noted that this "notice problem"—the difficulty biosimilar developers face in determining which manufacturing patents might be asserted against them—has led to prolonged delays in biosimilar launches, even after regulatory approval.[27] For example, Johnson & Johnson's use of newly acquired platform patents to delay the market entry of a Stelara (ustekinumab) biosimilar of Amgen until 2025, despite the expiry of its primary patent, illustrates how such patents can be strategically employed to delay competition.[28] The evidence thus indicates that the accumulation and assertion of manufacturing platform patents, often unrelated to genuine innovation, function as a critical barrier to timely biosimilar market entry.

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[22] See Srividya Ravi, *Patent Analysis for Medicines and Biotherapeutics in Trials to Treat COVID-19,* Research Paper No. 153 (Geneva: South Centre, 2022). Available from https://www.southcentre.int/wp-content/uploads/2022/04/RP153_Patent-Analysis-for-Medicines-and-Biotherapeutics-in-Trials-to-Treat-COVID-19_EN-1.pdf.

[23] I-MAK, Biologics, Biosimilars and Patents: A Beginner's Guide. Available from https://www.i-mak.org/wp-content/uploads/2024/05/Biologics-Biosimilars-Guide_IMAK.pdf.

[24] Osmat A. Jefferson, *et. al.,* "The puzzle of biologics manufacturing platform patents", *Nature Biotechnology*, vol. 43, 2025, pp. 295-9. Available from https://doi.org/10.1038/s41587-025-02579-y.

[25] Ibid., p. 296.

[26] Ibid., pp. 297-8.

[27] Ibid., p. 296.

[28] Jefferson et al. Reply, "Correspondence", *Nature Biotechnology,* vol. 43, 2025. Available from https://doi.org/10.1038/s41587-025-02765-y.

In view of the growing value of the global market for antibodies, patents covering antibodies are considered "the most valuable patents ever."[29] For example AbbVie, the originator of one of the world's bestselling mAbs — adalimumab (brand name - Humira) — filed 257 patent applications.[30] Almost 90 percent of these patent applications were filed after the marketing approval of adalimumab in the US in 2002, a decade after the first patent application on adalimumab was filed in 1994.[31] According to a report of the Committee on Oversight and Reform of the US House of Representatives, these patent applications were filed with the strategic intent to block competition from low-priced biosimilar versions of adalimumab.[32] While the primary patent on adalimumab expired in 2016, the effective period of patent protection in the US has been extended till 2037 on the basis of more than one hundred secondary patents that have been granted. As a result, Humira's price had risen to about $77,000 per year, and biosimilar competition in the US was delayed until January 2023 because nine biosimilar manufacturers chose to settle for licenses with AbbVie instead of litigating the extensive patent thicket. This delay cost US payers an estimated $77 billion.[33][34]

Other examples of mAbs with extensive patent thickets include pembrolizumab (Keytruda), trastuzumab (Herceptin), bevacizumab (Avastin), and rituximab (MabThera). Each of these products has a layered patent portfolio – encompassing basic patents, secondary patents on formulations, dosing regimens, and manufacturing processes – that effectively extends their market exclusivity and delays biosimilar entry. Additionally, biosimilar production of cetuximab (Erbitux) has faced similar challenges, with multiple patents creating significant barriers for competitors.[35]

IV.1.1. Challenges in patent examination and transparency

While in some cases biosimilar companies have been able to invalidate the secondary patents in Europe by successfully challenging them in court, this would not be a viable option for biosimilar companies in developing countries that have to ensure cost savings in order to supply the products at affordable prices. This makes it critical that unwarranted patent protection does not lead to price barriers in accessing mAbs, particularly in developing countries, by ensuring that patent protection is given to claims on monoclonal antibodies that constitute genuine inventions, i.e., that they rigorously meet the criteria of patentability.

A major challenge with regard to navigating around patents relating to biologics is that it is hard to identify the patent estate of a biologic drug that may be dispersed across many technologies and sub-categories, and consequently it is difficult to correctly examine all the patent claims relating to a biologic drug. There is also a lack of specific patent classification code either at the national or international level to categorize biologic related patent claims accurately.

A recent study on examination of patent applications relating to biologics in India from 2012 to 2018 found that patents have been granted on 329 mAbs and that 46 patent applications on

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[29] Mark A. Lemley and Jacob S. Sherkow, "The Antibody Patent Paradox", *The Yale Law Journal*, vol. 132 (No. 4), 2023, p. 1011. Available from https://www.yalelawjournal.org/article/the-antibody-patent-paradox.

[30] I-MAK, Fact Sheet: Humira, November 2020, Available from https://www.i-mak.org/wp-content/uploads/2020/11/HumiraFactSheet_85x11.pdf.

[31] I-MAK, Overpatented, Overpriced: Humira. October 2020. Available from https://www.i-mak.org/wp-content/uploads/2020/10/i-mak.humira.report.3.final-REVISED-2020-10-06.pdf.

[32] U.S. House of Representatives, Drug Pricing Investigation – AbbVie – Humira and Imbruvica, Staff Report, Committee on Oversight and Reform, May 2021. Available from https://docs.house.gov/meetings/GO/GO00/20210518/112631/HHRG-117-GO00-20210518-SD007.pdf.

[34] I-MAK, ITC Adalimumab submission, 3 January 2022. Available from https://www.i-mak.org/wp-content/uploads/2022/02/ITC-Adalimumab-Submission-I-MAK-3-Jan-2022.docx.pdf.

[35] Evelien Moorkens *et. al.,* "An overview of patents on therapeutic monoclonal antibodies in Europe: are they a hurdle to biosimilar market entry?", *mAbs*, vol. 12 (No. 1), 2020, e1743517. Available from https://doi.org/10.1080/19420862.2020.1743517.

mAbs were rejected.[36] Monoclonal antibody patent claims may cover antigens, epitopes, nanobody,[37] polyclonal antibody, fusion protein,[38] Fab or Fv fragments,[39] scFV peptide,[40] nucleic acid code of antibody region, bispecific antibody,[41] modified antibodies, epitopes on antigens, paratopes on antibodies, domain antibodies,[42] conjugated antibodies,[43] chimeric antibodies,[44] humanized antibodies[45] and human antibodies. Patent claims on mAbs have been most often objected to under Section 3(d) of the Indian patent law for being merely a new form or new use of a known substance without demonstrating any enhanced efficacy, and under Sections 3(e) and 3(c) for claims that represent mere admixtures or the isolation of substances that already occur in nature. These objections typically arise in cases where applicants seek patent protection for antibody variants, formulations, or combinations, yet fail to provide sufficient experimental evidence of a technical or therapeutic advantage over the prior art. Applicants try to overcome Section 3 objections by amending the claim scope and providing detailed efficacy data to demonstrate a technical advantage. Applicants may overcome Section 3 objections by narrowing the claim scope and submitting detailed working examples and efficacy data to demonstrate unexpected technical advantages over known antibodies, thereby proving the invention's inventive step. When these submissions are accepted, the objections are waived and the patent is granted, although inconsistent application of these criteria highlights the need for clearer examination guidelines. The study concludes that many applications are approved without detailed reasoning on how these objections were overcome.[46]

These inconsistencies in patent examination practices relating to mAbs are symptomatic of a deeper malaise that afflicts many patent offices worldwide – the lack of clear regulations and guidelines for the examination of patent claims on biologics, including mAbs. Without clear criteria for the examination of patent applications for biologics, the process remains

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[36] Achal Prabhala et al., Monopolies on Biologics, including Vaccines: The Case for Reform in Intellectual Property and Pharmaceutical Regulation", AccessIBSA and Third World Network (2023). Available from https://www.twn.my/title2/books/pdf/Monopolies%20on%20Biologics,%20including%20Vaccines.pdf.

[37] A nanobody is a small, single-domain antibody derived from the heavy-chain antibodies found in camelids (like camels or llamas). Unlike traditional antibodies, nanobodies are much smaller, typically around 15 kDa, and maintain the ability to bind to specific antigens. Due to their small size, nanobodies have advantages, such as better tissue penetration and the ability to reach difficult targets, making them useful in diagnostics and therapeutics.

[38] A fusion protein is created by joining two or more genes that originally encoded separate proteins, resulting in a single polypeptide that combines the functional properties of its parts. These engineered proteins are commonly used in research, diagnostics, and therapeutics to improve protein stability, target specific cells, or study protein interactions.

[39] Fab fragments (short for "fragment antigen-binding") are portions of an antibody that contain one constant and one variable domain from both the heavy and light chains, retaining the antigen-binding site. In contrast, Fv fragments consist solely of the variable regions of the heavy and light chains, which can be linked together to form a single-chain variable fragment (scFv), offering a smaller size and enhanced tissue penetration.

[40] An scFv (single-chain variable fragment) peptide is a small antibody fragment that consists of the variable regions of the heavy and light chains of an antibody, linked together by a flexible peptide linker. It retains the ability to bind to the target antigen, but due to its smaller size compared to full antibodies, it can penetrate tissues more easily and be used in diagnostics or targeted therapies.

[41] Bispecific antibodies are engineered molecules that have two distinct antigen-binding sites, allowing them to simultaneously target two different antigens or epitopes.

[42] Domain antibodies (dAbs) are the smallest functional fragments of antibodies, consisting of a single variable domain (either V_H or V_L) that retains the ability to bind to an antigen. These compact molecules offer advantages such as improved tissue penetration, enhanced stability, and ease of genetic engineering, making them useful in both therapeutic and diagnostic applications.

[43] Conjugated antibodies are antibodies that have been chemically linked to another molecule, such as a drug, toxin, radioactive isotope, or fluorescent dye. This design allows the antibody to target specific cells and deliver the attached payload directly, which is useful in therapies (like antibody-drug conjugates) and diagnostic applications.

[44] Chimeric antibodies consist of the entire variable region from a non-human source (typically mouse) fused with human constant regions, making them roughly 65–70 percent human. In contrast, humanized antibodies involve grafting only the antigen-binding loops (CDRs) from the non-human antibody onto a human antibody framework, resulting in a molecule that is about 90% human and generally less immunogenic.

[45] Prabhala et al.*, supra* note 36.

[46] Ibid.

unstructured and is prone to misinterpretation, confusion, inconsistency and the proliferation of “evergreening” patents.

A potential solution to this challenge is to develop clear, standardized examination guidelines that define precise criteria for what constitutes novelty and inventive step in the case of mAbs, such as enhanced efficacy and unexpected technical advantage, ensuring that objections under patent law are applied uniformly. Second uses of a known mAb should not be deemed patentable in countries where industrial applicability is required, the full and precise disclosure of the invention should be ensured as well as compliance with the essential standard of unity of invention. Requiring examiners to provide detailed reasoning in their decision orders and implementing regular training sessions would promote transparency and consistency, ultimately reducing uncertainty for applicants and improving the patent examination process. This is a common need in many developing countries.

For example, a recent South Centre study on patent examination of claims on mAbs in Argentina made similar findings as the situation in India. The study found that most patent applications for mAbs in Argentina focus on product claims, with many granted without detailed examiner reasoning, suggesting that the current evaluation process may be too lenient and inconsistent. It concludes that the existing patent examination practices for mAbs do not adequately address issues of novelty, inventive step, and unity of invention, which may lead to overly broad patents that hinder competition. The authors recommended revising and clarifying these guidelines to ensure a more rigorous and transparent assessment process.[47] A recent empirical study found that the use of pharmaceutical patent examination guidelines developed for pharmaceuticals produced by chemical synthesis adopted in 2012 has resulted in a high rejection rate for secondary patents, aligning legal practice with policy objectives.[48] Even though the Argentinean patent office (National Institute of Industrial Property) included in its patentability guidelines a section directed to biotechnological inventions by means of Resolution INPI N° P-283 of September 25, 2015, they did not provide specific indications regarding inventions related to antibodies.

The difficulties in identifying and examining patent applications on biologics also makes it difficult to use flexibilities like compulsory licensing to override patents where they impede the public health need of access to medicines. As most laws require listing of specific patents against which compulsory license is intended to be invoked, the difficulty in identifying them becomes a significant challenge. In this light, some experts suggest that it may be pertinent to explore if national laws could allow compulsory licenses to be issued over a product as a whole, or for specific platform technologies, without the requirement of having to identify all relevant patents.[49]

IV.2 Data Exclusivity and Trade Secrets

Intellectual property protection can also be a critical factor with regard to access to test data produced by the originator of a biologic drug, for obtaining marketing authorization of a biosimilar by a regulatory authority. Article 39.3 of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) states that

[47] Juan Correa et al*., Pautas para el examen de patentes sobre anticuerpos monoclonales*, Research Paper No. 192 (Geneva: South Centre, 2024). Available from https://www.southcentre.int/documento-de-investigacion-192-30-de-enero-de-2024/.
[48] Nirmalya Syam, ”Argentina sets precedent in combating evergreening with rigorous patent examination guidelines”, *SouthNews*, No. 491, 6 June 2024. Available from SouthNews: Argentina Sets Precedent in Combating Evergreening with Rigorous Patent Examination Guidelines (mailchi.mp).
[49] Prabala, et al., *supra* note 35, p. 66.

> *Members, when requiring, as a condition of approving the marketing of pharmaceutical or of 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.*

An important condition for the application of article 39.3 of the TRIPS Agreement is that the data must be relating to a "new chemical entity" – a term that is not defined in the Agreement. Generally, the term refers to small molecules produced through chemical synthesis, and hence, biologics seem to be excluded from the scope of article 39.3. Moreover, the TRIPS Agreement does not require that test data should be protected through exclusive rights, but only protected against "unfair commercial use."[50] Nevertheless, data exclusivity for biologics has been made a specific requirement in some free trade agreements (FTAs).[51] Implementation of TRIPS-plus data exclusivity obligations in relation to biologics can be made even more onerous for developing countries in situations where developed country partners to the FTA subject them to unilateral certification procedures regarding full and adequate implementation of such obligations with no flexibility for policy space.[52] Therefore, it is crucial that developing countries avoid FTA obligations that enforce data exclusivity on test data and instead secure robust public health safeguards.

Under the current regulatory framework, developing a biosimilar quickly is extremely challenging without access to technical know-how and manufacturing information. Sharing dossier information between regulatory authorities can reduce redundant work, lower the resources needed to approve biologics and speed up their market entry, while ensuring that biosimilars match the originator's product safety, efficacy, and purity. This approach can reduce the need for excessive clinical testing—improving patient safety—and streamline the market entry of competitive biosimilars. Sharing of dossier information would not constitute an unfair commercial exploitation of the test data and would be justifiable on public health grounds.

Besides exclusivity to test data, trade secret protection of the technical know-how including research data, cell-lines, sequence ID, vectors, constructs, media conditions, method of isolation, storage conditions and manufacturing processes can be used to perpetually protect such know-how, without which a biosimilar cannot be developed at substantially reduced time and cost. In this regard it is worth considering that nothing in the TRIPS Agreement prevents national IP laws from subjecting trade secrets to compulsory licensing.[53] Much of this information is also submitted by the originator seeking marketing approval to a regulatory authority and is part of the regulatory dossier. Nothing in the TRIPS Agreement, as noted, restricts the sharing of such dossier information in the public interest.

In sum, by strengthening patent examination, promoting the use of the TRIPS flexibilities, and resisting extended test data exclusivity provisions, as well as making exceptions to trade secret

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[50] See Carlos M. Correa, *Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement* (Geneva: South Centre, 2004).

[51] See AJMC – The Center for Biosimilars, Exclusivity for Biologic Products under the USMCA: What is Changing, and What Happens Next?, 14 August 2019. Available from https://www.centerforbiosimilars.com/view/exclusivity-for-biologic-products-under-the-usmca-what-is-changing-and-what-happens-next.

[52] See Carlos M. Correa, *Mitigating the Regulatory Constraints Imposed by Intellectual Property Rules under Free Trade Agreements*, Research Paper No. 74 (Geneva: South Centre, 2017), pp. 7-8. Available from https://www.southcentre.int/wp-content/uploads/2017/02/RP74_Mitigating-the-Regulatory-Constraints-Imposed-by-Intellectual-Property-Rules-under-Free-Trade-Agreements_EN-1.pdf.

[53] Olga Gurgula, "Accelerating COVID-19 Vaccine Production via Involuntary Technology Transfer", Policy Brief No. 102, South Centre, Geneva, September 2021. Available from https://www.southcentre.int/policy-brief-102-september-2021/#more-17137.

protection, developing countries can improve access to affordable mAbs. Such policies would also promote genuine innovation.

V. MARKET ACCESS BARRIERS

V.1 Limited Market Prioritization and Registration Challenges

Many mAbs are not registered in developing countries, rendering them unavailable to local populations. Pharmaceutical companies often prioritize lucrative developed country markets.[54] This reflects a market incentive–driven approach that neglects the needs of developing countries. This approach leaves significant gaps in product availability for populations in developing countries.[55]

V.1.1 Dominance of private industry and underinvestment in global health needs

Major pharmaceutical and biotechnology companies dominate mAb R&D efforts and production, as they possess the necessary workforce, materials, and financial capacity to carry out extensive R&D, as well as oversee the development, production, and regulatory approval of new mAbs. According to a 2015 study, among the top 25 entities engaged in mAb-related R&D, the only public sector organization represented is the US Department of Health and Human Services (HHS).[56] Given that the private industry dominates the mAb R&D landscape—with little public sector involvement—there is insufficient incentive to ensure equitable global distribution, especially for diseases that primarily affect developing countries.

This issue is even more pronounced for infectious diseases. Unlike oncology or autoimmune diseases—where high-income markets provide strong commercial incentives—mAbs for infectious diseases rely heavily on funding from donor agencies rather than private investment. However, donor-based funding remains limited and unpredictable, further limiting the prospects of increasing access.[57]

V.1.2 Public funding and market-shaping interventions

To counteract these market-driven disparities, it is essential to implement strategic market-shaping interventions. Increased public funding for mAb R&D is crucial for addressing unmet health challenges in developing countries. Push funding, such as government grants and subsidies, can help drive R&D for mAbs in areas where commercial market potential is low.[58]

Additionally, alternative business models and industry-led access initiatives offer potential solutions, though they often face scalability and sustainability challenges. For instance, the Utrecht Centre for Affordable Biotherapeutics (UCAB), a partnership between the WHO and Utrecht University, and the IAVI-Serum Institute collaboration aim to reduce costs, but their long-term viability remains uncertain due to fluctuating market demand and funding constraints.[59] Similarly, corporate-led initiatives like Roche's Herceptin Access Program and Takeda's Global Access Program have improved access in some low- and middle-income

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[54] Wellcome-IAVI, *supra* note 13.
[55] See generally World Health Organization, *Public health, innovation and intellectual property rights: Report of the Commission on Intellectual Property Rights, Innovation and Public Health* (Geneva: World Health Organization, 2006). Available from https://iris.who.int/server/api/core/bitstreams/6e7f9d06-c5df-41a5-9fc6-5bb07ca1d953/content.
[56] Xiaomei Geng et al., "Research and development of therapeutic mAbs: An analysis based on pipeline projects", *Human Vaccines & Immunotherapeutics*, vol. 11 (No. 12), 2015, pp. 2769-76. Available from https://pmc.ncbi.nlm.nih.gov/articles/PMC4916486/pdf/khvi-11-12-1074362.pdf.
[57] Wellcome-IAVI, *supra* note 13, p. 40.
[58] Malhotra et al., *supra* note 5.
[59] Ibid.

countries (LMICs), but they rely on temporary corporate subsidies rather than systemic reforms, limiting their long-term sustainability.[60]

To bridge these gaps, public-sector participation must increase through international collaborations and policy-driven R&D incentives. Expanding government investment in biosimilar mAbs and fostering technology transfer initiatives can help enhance affordability while reducing reliance on high-cost originator biologics.

V.1.3 Country-specific public funding initiatives for mAbs development

Several developing countries have taken proactive steps to support mAb R&D through public investment and strategic initiatives. Some examples are:

India: India has made significant strides in mAbs development through public funding and strategic initiatives aimed at both infectious and non-communicable diseases. The National Biopharma Mission (NBM), launched by the Department of Biotechnology (DBT), provides funding for translational research, technology transfer, and manufacturing infrastructure to accelerate indigenous biologics production.[61] Additionally, the Biotechnology Industry Research Assistance Council (BIRAC) supports R&D for both novel and biosimilar mAbs, with the aim of ensuring affordability and accessibility.[62] Public-private partnerships have further strengthened India's mAbs ecosystem, with government-backed collaborations involving Biocon, Serum Institute of India, and other key players.[63]

Brazil: Brazil has been a leader in publicly funded biopharmaceutical development, particularly through product development partnerships (PDPs), which promote technology transfer agreements between international manufacturers and local producers. These PDPs enable Brazilian institutions, such as Bio-Manguinhos/Fiocruz, to manufacture biosimilar and innovative mAbs at reduced costs for the public health system.[64] The Brazilian Development Bank (BNDES) also plays a key role, providing funding for mAbs R&D and local production initiatives.[65] Additionally, the government supports continuous processing biomanufacturing, such as at the Instituto Butantan's facility, which is expected to enhance the country's production capacity.[66]

Argentina: Argentina has invested in the local production of biosimilars and mAbs through state-backed programmes that support domestic manufacturers like mAbxience, which operates a government-supported biomanufacturing facility using single-use bioreactors.[67] The Argentine Government provides financial incentives and regulatory support to ensure that locally produced mAbs are available at lower costs.[68] These efforts align with Argentina’s broader biopharmaceutical strategy, which seeks to expand public-private collaborations to enhance national self-sufficiency in biologics.[69]

Cuba: Cuba has built a strong public-sector-driven biopharmaceutical industry, with state-owned institutions like the Center for Molecular Immunology (CIM) leading the development of innovative and biosimilar mAbs.[70] These efforts are fully funded by the government, ensuring that mAbs are developed not only for domestic use but also for export to other developing

[60] Ibid., p. 42.
[61] Ibid., p. 41.
[62] Ibid., p. 42.
[63] Ibid., p. 44.
[64] Ibid., p. 49.
[65] Ibid., p. 50.
[66] Ibid., p. 52.
[67] Ibid., p. 53.
[68] Ibid., p. 54.
[69] Ibid., p. 56.
[70] Ibid., p. 57.

countries.[71] Cuba's nationalized healthcare system integrates mAb research and production, facilitating rapid clinical translation and affordability.[72] The country has also pioneered novel mAb-based treatments, particularly for oncology and autoimmune diseases, positioning itself as a leader in publicly funded biologics.[73]

China: China has significantly advanced its mAbs R&D through strategic public-sector investments and government-led initiatives. The "Made in China 2025" plan, introduced in 2015, prioritizes biopharmaceuticals as one of ten critical sectors for national development, aiming to reduce reliance on foreign technology and promote domestic innovation.[74] Under this framework, the China National Biotec Group (CNBG), a state-owned enterprise, has been instrumental in developing and producing mAbs. Notably, the CNBG recombinant human monoclonal antibody, F61, received approval for clinical trials in July 2022, demonstrating high neutralizing activity against various SARS-CoV-2 variants, including Omicron sub-variants.[75]

While national efforts have shown potential, their scalability remains constrained without a coordinated multilateral funding mechanism that pools resources, ensures equitable access, and strengthens regulatory harmonization across countries.

While these national initiatives demonstrate progress, they remain fragmented and lack a global coordination mechanism, making scalability and long-term sustainability a challenge. These initiatives demonstrate the potential of state-backed funding, technology transfer, and public-private partnerships in expanding local manufacturing and thereby enhancing access to affordable mAbs. Yet, without a multilateral cooperative framework, such efforts may be fragmented, limiting their global impact and scalability.

V.1.4 Need for multilateral coordination and sustainable funding

Despite strong national efforts, sustainable mAb R&D in developing countries requires a multilateral cooperative framework. Current efforts are largely country-specific and may not effectively address global accessibility challenges. Without international resource pooling, many of these initiatives risk being underfunded, failing to achieve widespread impact.[76]

A coordinated global approach—similar to mechanisms seen in vaccine development—could help ensure equitable investment in mAb innovation and distribution. Any public funding for mAb R&D should also include strict technology transfer and access provisions, ensuring affordability, local production capacity, and widespread registration in developing markets.

By establishing a globally coordinated, publicly funded mAb R&D framework, governments and international organizations can counteract the profit-driven limitations of private industry. This model would:

1. Support equitable access by ensuring that mAb therapies reach LMICs, rather than being confined to high-income markets.

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[71] Ibid., p. 58.
[72] Ibid., p. 60.
[73] Ibid., p. 61.
[74] Center for Strategic and International Studies (CSIS), Made in China 2025, 2015. Available from https://www.csis.org/analysis/made-china-2025.
[75] Global Times, "China-developed recombinant human monoclonal antibody enters clinical trials", 26 July 2022. Available from https://www.globaltimes.cn/page/202207/1271433.shtml.
[76] See Unitaid, Novel business models for accessible monoclonal antibodies for infectious diseases in low-and middle-income countries: Recommendations from a multistakeholder meeting convened by IAVI, Unitaid, the Medicines Patent Pool and Wellcome, Geneva, Switzerland, 9-10 March 2023, p. 9. Available from https://unitaid.org/uploads/Novel-business-models-for-accessible-monoclonal-antibodies-for-infectious-diseases-in-low-and-middle-income-countries.pdf.

2. Sustain the product development continuum, from early discovery to post-market introduction.
3. Facilitate technology transfer, reducing reliance on expensive originator biologics.[77]

[77] Ibid.

VI. REGULATORY BARRIERS

Delays in regulatory approval and limited incentives for pharmaceutical companies to register mAbs in developing countries significantly hinder accessibility. Many national regulatory authorities (NRAs) in these countries operate with resource constraints, unclear regulatory frameworks, and lengthy approval processes.[78] As a result, companies often find it too costly and time-consuming to register their products, forcing regulators to outsource key review functions, which can lead to inconsistencies and further delays.[79] Consequently, both biosimilars and innovative mAbs take longer to enter developing markets, prompting calls for streamlined regulatory pathways.

VI.1 Existing Regulatory Pathways and Their Limitations

Several models have been proposed to expedite mAb registration, including the WHO Prequalification Programme, the European Medicines Agency (EMA) Article 58 Pathway, Swissmedic, and the PEPFAR tentative approval process. However, these frameworks have seen limited uptake for mAbs. To date, the WHO Prequalification Programme has only approved three biosimilar mAbs—trastuzumab (2019) for breast cancer, rituximab (2020) for blood cancers, and tocilizumab (2022) for COVID-19 treatment. This slow progress highlights the need for greater regulatory reliance and efficiency to accelerate approvals.

To facilitate faster reviews, the WHO Collaborative Registration Procedure (CRP) allows NRAs to leverage assessments from Stringent Regulatory Authorities (SRAs) or WHO prequalification reports, reducing duplicative evaluations. Traditionally, an SRA is a regulatory body that is a member or observer of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) or has a legally binding mutual recognition agreement with an ICH member.[80] However, recognizing the limitations of this model, the WHO in 2021 replaced the term SRA with WHO-Listed Authority (WLA) to promote a more inclusive regulatory framework, acknowledging competent agencies beyond developed countries. This change aimed to acknowledge a broader range of regulatory authorities beyond those traditionally associated with developed countries and the ICH. This shift could also be intended to address concerns about the influence of large pharmaceutical companies in setting regulatory standards by the ICH.[81]

VI.2 WHO-Listed Authority (WLA) Framework: Challenges and Opportunities

The WHO Global Benchmarking Tool (GBT) now serves as a global framework to evaluate regulatory systems using sub-indicators and cross-cutting themes, assessing various product types—including medicines, vaccines, medical devices, and blood products. National regulatory authorities (NRAs) are categorized on a maturity scale from 1 to 4; those achieving an overall maturity level 3 (ML3) are eligible for further performance evaluation, and high-

[78] WHO, "Regulatory requirements: an assessment of global Chemistry, Manufacturing and Controls (CMC) regulatory requirements in low and middle income countries", WHO Drug Information, vol. 32 (No. 3), 2018, p. 404. Available from https://iris.who.int/bitstream/handle/10665/330905/DI323-400-406-eng.pdf?sequence=1&isAllowed=y.

[79] Wellcome-IAVI, *supra* note 13, p. 21.

[80] Revive by GARDP, Stringent regulatory authority. Available from https://revive.gardp.org/resource/stringent-regulatory-authority-sra/?cf=encyclopaedia.

[81] See Ayelet Berman, "The Public-Private Nature of Harmonization Networks", CTEI Working Paper, CTEI-2011-06. Available from https://repository.graduateinstitute.ch/record/294798/files/CTEI-2011-06.pdf?subformat=pdfa&version=1.

performing authorities are subsequently designated as WLAs. This process is entirely voluntary, and as of May 2024, 32 authorities from 31 countries have been listed as WLAs.

While the WLA framework promotes regulatory harmonization, its modular evaluation approach—where each function or product category is assessed separately—adds complexity, requiring additional documentation, expertise, and financial investment. Consequently, despite its potential, many international procurement agencies remain hesitant to abandon traditional SRA approvals due to concerns over protracted reviews and inconsistencies in implementation.

Moreover, the performance evaluation of a regulatory authority for being listed as a WLA is based on full compliance by the regulatory authority with international standards and guidelines, which not only includes WHO standards and guidelines but also guidelines set by other fora such as the ICH. The drug quality standards advocated by ICH have sometimes increased manufacturing costs without providing any public health benefit. Such standards can adversely impact competition, which is much needed in the mAbs space, while not adding to the quality, safety or efficacy of the drug.

For example, ICH Q5E—"Comparability of Biotechnological/Biological Products Subject to Changes in Manufacturing Process"—provides recommendations that are relevant for demonstrating comparability, a key aspect of biosimilar development. The ICH Q5E guideline states that if basic laboratory tests do not clearly show that a manufacturing change has not affected a product's quality, safety, or effectiveness, then additional studies are needed. These extra tests—such as those that measure how the product works in the body or check for side effects—should directly compare the product before and after the change, with the exact studies chosen based on how complex the product is and what is already known about it.[82] The requirement of comparative clinical trial was subsequently incorporated into the WHO Guidelines on Evaluation of Similar Biotherapeutic Products in 2009.[83]

VI.3 Overcoming the Burden of Comparative Clinical Trials and Animal Studies for Biosimilars

Many developing countries adopted the 2009 WHO Guidelines and made comparative clinical trials mandatory for marketing approval of biosimilars. In accordance with these "WHO" guidelines, a non-originator seeking marketing approval must conduct a comparative clinical trial with 200–400 subjects—half receiving the originator's product and half the biosimilar—to demonstrate efficacy and safety. However, the extremely challenging sourcing of the originator product, which accounts for nearly 50 percent of development costs, makes the process unaffordable for many patients, especially in developing countries.

The WHO SBP Guidelines were revised in 2022 on the basis of scientific evidence that structural tests in the laboratory can reliably show product similarity making it unnecessary to conduct comparative clinical trials unless critical quality attributes related to manufacturing do not match. Besides waiving the comparative clinical trial requirement when robust analytical and functional data can demonstrate high similarity, the revised WHO SBP Guidelines have also waived the requirement for conducting animal studies. In December 2022, the United States Food and Drug Administration (USFDA) passed the FDA Modernization Act 2.0,[84] which allowed the country's Food and Drug Administration to do away with animal testing for the

[82] ICH, ICH Harmonized Tripartite Guidelines: Comparability of Biotechnological/Biological Products Subject to Changes in their Manufacturing Process, Q5E, 18 November 2004. Available from https://database.ich.org/sites/default/files/Q5E%20Guideline.pdf.
[83] Sengupta, *supra* note 19, p. 28.
[84] FDA Modernization Act 2.0 available at < https://www.congress.gov/bill/117th-congress/senate-bill/5002/titles>

purposes of drug and biological product applications**.** Similarly other jurisdictions like UK,[85] the European Union (EU[86]) and Canada[87] have moved away (or are in the process of doing so) from animal testing for biosimilar approval**.** This relaxation of the regulatory requirement is expected to further reduce development cost for biosimilars.

However, even though the WHO SBP Guidelines have been revised in 2022, many regulatory authorities in developing countries continue to have the requirement of comparative clinical trials as mandatory for approval of biosimilars.

In summary, while the revised WHO SBP Guidelines now allow reliance on robust structural analyses in lieu of costly comparative clinical trials, many developing countries continue to enforce comparative clinical trial and animal studies requirements, thereby imposing significant financial and procedural burdens on the approval of biosimilars. This persistent disconnect underscores an urgent need for WHO to exhort regulatory authorities to follow its updated standards—such as the revised SBP Guidelines—instead of defaulting to outdated international benchmarks like the ICH guidelines, thereby streamlining approval processes, reducing development costs, and ultimately enhancing patient access to essential mAbs worldwide.

It should also be noted that even the revised WHO SBP guidelines lay down some requirements that have to be met in order to waive comparative clinical trials for biosimilars. The most significant requirement is that the biosimilar product must be structurally comparable to a reference biological product (originator product) that has been marketed for a suitable period of time with proven quality, safety and efficacy. However, the period of time for which the reference biological product should be in the market has not been defined. This requirement implies that in effect no biosimilar can be introduced immediately after a new biologic drug is put on the market.

VI.4 Need for Greater Regulatory Alignment and Information Sharing

While the general focus for enabling registration of mAbs has been on regulatory harmonization with the expectation of increasing regulatory reliance based on harmonized standards, compliance with applicable standards by a reference regulatory authority in itself will not enable reliance on its assessment by another regulatory authority, unless the complete regulatory dossier information is shared with that authority. In this context, the WHO notes that

> "Lack of access to complete assessments of reference regulatory authorities can be a major barrier to effective reliance. Reference regulatory authorities should make their assessments and other regulatory information publicly available. Non-public regulatory reports might be available directly from the manufacturer when the company is able to access these reports from the reference regulatory authority. If this is not possible, the relying NRA should approach the reference regulatory authority. In these cases,

[85] Medicines & Healthcare products Regulatory Agency, Guidance on the licensing of biosimilar products, Updated 27 February 2025. Available from https://www.gov.uk/government/publications/guidance-on-the-licensing-of-biosimilar-products/guidance-on-the-licensing-of-biosimilar-products.

[86] European Medicines Agency, Reflection paper on a tailored clinical approach on biosimilar development, 17 March 2025, p. 10. Available from https://www.ema.europa.eu/en/documents/other/reflection-paper-tailored-clinical-approach-biosimilar-development_en.pdf.

[87] Health Canada, Guidance document: Information and submission requirements for biosimilar biologic drugs (2025-Revised draft), 10 June 2025, p. 6 Available from https://www.canada.ca/content/dam/hc-sc/documents/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/applications-submissions/guidance-documents/information-submission-requirements-biosimilar-biologic-drugs/draft-biosimilars-guidance-external-consultation-eng.pdf.

> arrangements among NRAs on the exchange of confidential information would facilitate the reliance process."[88]

Such confidential information can include test data submitted by the originator, as well as know-how relating to the manufacturing and use of the biologics. In this regard, it will be pertinent to explore possible exceptions to the protection of undisclosed information against unfair commercial use or exclusivity for data submitted to regulatory authorities by manufacturers.

In addition to sharing dossier information, regulatory authorities can also play a significant role in enabling access to critical know-how about the cell lines of the originator with the biosimilar developers. The originator could be required to deposit the cell line used with the regulatory authority at the time of obtaining marketing authorization, and this can be shared with qualified biosimilars manufacturers. The knowledge of the cell line will enable biosimilars to achieve similarity with the originator with a greater degree of precision, and also save the significant cost incurred in developing the suitable cell line on their own.

[88] WHO, *WHO Expert Committee on Specifications for Pharmaceutical Preparations*, Fifty-Fifth Report, WHO Technical Report Series 1033 (World Health Organization: Geneva, 2021), pp. 253-4. Available from https://iris.who.int/bitstream/handle/10665/340323/9789240020900-eng.pdf?sequence=1

VII. MANUFACTURING AND SUPPLY CHAIN LIMITATIONS

Manufacturing mAbs is a multi-stage process that begins with the identification and selection of the target antibody, followed by the development of a high-yielding cell line, mostly using Chinese Hamster Ovary (CHO) cells or other mammalian systems like HeLA cells.[89] The subsequent cell culture process involves harvesting and purification to remove impurities.

Commercial manufacturing of recombinant mAbs begins with the development of a stable cell line—typically using genetically engineered host cells like CHO cells—to produce both the heavy and light chains of the antibody.[90] Once the cell line is established, the cells are expanded in a seed train and then cultured in large-scale bioreactors where they secrete the antibody into the culture medium;[91] the antibody is subsequently harvested, purified through filtration and chromatography steps, formulated into a final therapeutic product,[92] rigorously tested for quality, and finally packaged for distribution. Where conventional hybridoma technology is used, the selected hybridoma cells are similarly cultured in bioreactors and follow the same process.

In general, recombinant DNA technology is more expensive to set up because it involves complex genetic engineering steps, such as isolating and cloning the antibody genes and developing stable cell lines, whereas conventional hybridoma methods – though simpler – are often less suited for large-scale commercial production. However, the higher cost of recombinant methods is offset by benefits like increased consistency, scalability, and the ability to fine-tune the antibody for better performance, making it the preferred approach for commercial manufacturing.[93]

In commercial manufacturing the cell culture process usually begins with a fed-batch culture phase in large bioreactors that lasts about 10 to 15 days, during which the cells are fed with nutrients to grow and produce the antibody. Once the desired concentration of antibody is reached, it is harvested from the mammalian cell culture through the removal of cellular debris, cell fragments and other impurities.[94] After harvest, the antibody is purified using a series of chromatographic steps over roughly two to three days,[95] and then the purified product is formulated—typically in about one day on the production line—although developing the optimal formulation during R&D may take several months. This involves a long production time and high cost of materials. It costs $95-200 per gram to produce a marketed mAb without factoring in R&D costs. The cost for start-ups will be much higher. If several grams of monoclonal antibody product are required then this will likely not be affordable for most developing countries. In disease segments such as infectious diseases, where vaccines and small molecule pharmaceutical drugs are available at substantially lower costs, the high cost of

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[89] Megan Thomas, "Where do we stand with cell line development?", *Drug Discovery World*, 5 March 2025. Available from https://www.ddw-online.com/where-do-we-stand-with-cell-line-development-33804-202503/.

[90] Feng Li, et al., "Cell culture processes for monoclonal antibody production", *MAbs,* vol. 2, no. 5, 2010, pp. 466-77. Available from https://pmc.ncbi.nlm.nih.gov/articles/PMC2958569/.

[91] Wen-Jing Xu, et al., "Progress in fed-batch culture for recombinant protein production in CHO cells", *Applied Microbiology and Biotechnology*, vol. 107 (no. 4), 2023, pp. 1063-75. Available from https://pmc.ncbi.nlm.nih.gov/articles/PMC9843118/.

[92] Hui F. Liu, et al., "Recovery and purification process development for monoclonal antibody production", *MAbs*, vol. 2 (no. 5), 2010, pp. 480-99. Available from https://pmc.ncbi.nlm.nih.gov/articles/PMC2958570/.

[93] Geneviz, "Monoclonal Antibody Production: Hybridoma vs. Recombinant, 19 February 2025. Available from https://blog.genewiz.com/monoclonal-antibody-production-hybridoma-vs.-recombinant

[94] Maribel Rios, " A Decade of Harvesting Methods", *BioProcess International*, 1 June 2012. Available from https://www.bioprocessintl.com/chromatography/a-decade-of-harvesting-methods.

[95] ThermoFisher, Antibody Purification Methods. Available from https://www.thermofisher.com/ch/en/home/life-science/antibodies/antibodies-learning-center/antibodies-resource-library/antibody-methods/antibody-purification-methods.html#:~:text=purification%20of%20antibodies-,Introduction%20to%20antibody%20purification,to%20antibody%20class%20or%20isotype.

production of mAbs is even more unsustainable. Thus, new manufacturing processes, innovative facilities, and alternative cell lines are being explored as ways to further lower production costs.

The cost of production of mAbs is also influenced by the mode of delivery or administration of the mAb and its packaging. Monoclonal antibodies are generally delivered intravenously, subcutaneously or through nasal administration. Delivery of mAbs by these methods means that they must be administered by a medical professional, leading to high delivery costs. Therefore, alternative modes of administration of mAbs, including through oral delivery, are being explored. Innovative approaches to packaging and storage are also being explored to make mAbs more affordable through lowering packaging costs.

Shipping mAbs is challenging because their instability at ambient temperatures requires costly cold storage, a problem in several developing countries with limited cold-chain capacity and frequent power outages. Developing cost-effective cold-chain technologies or thermostable mAb formulations that allow ambient storage could make these therapies more affordable and accessible.

VII.1 Technological Innovations in mAbs Manufacturing

A number of technological innovations today can make it possible to reduce the cost of manufacturing and achieve economies of scale for biologics.

VII.1.1 Single-Use Technologies (SUT)

Single-Use Technologies (SUT) represent a game-changing innovation for production of mAbs and other biologics at low cost. Traditional stainless-steel bioreactors require costly cleaning, sterilization, and maintenance, increasing operational expenses. SUT eliminates the need for clean-in-place (CIP) and sterilize-in-place (SIP) procedures, reducing labour, water, and energy costs.[96] Single-Use Technologies allow for flexible facility design, enabling quick adaptation to different production scales. Biopharmaceutical companies can set up modular manufacturing units, adjusting production volumes based on market demand. Single-Use Technologies accelerate facility setup and reduces downtime between batches, expediting biosimilar production. This speed is crucial for rapid market entry, especially in response to public health emergencies.

Since SUT systems are disposable, each production batch starts with a sterile environment. This minimizes contamination risks and ensures consistent quality in biosimilar production, and facilitates regulatory compliance.

By reducing costs, increasing flexibility, and improving production efficiency, SUT makes biologics manufacturing more accessible, particularly in developing countries. As the global demand for biosimilars grows, the adoption of SUT can help bridge the affordability gap, ensuring wider access to life-saving monoclonal antibody therapies. Regulatory bodies and industry stakeholders must work together to promote SUT adoption while addressing challenges related to waste management, supply chain stability, and validation processes.

[96] "How single-use technologies can improve antibodies production", *Drug Discovery World,* 7 May 2024. Available from https://www.ddw-online.com/how-single-use-technologies-can-improve-antibodies-production-29621-202405/.

VII.1.2 Modular and continuous manufacturing

Modular manufacturing refers to a facility design approach where bioprocessing units (e.g., bioreactors, purification systems, and storage units) are pre-fabricated, transportable, and rapidly deployable. Instead of constructing a traditional large-scale biomanufacturing plant, modular facilities can be built off-site, shipped, and assembled on-site, reducing setup time and cost. The introduction of modular biomanufacturing facilities that can be rapidly assembled and scaled presents another opportunity to enhance mAb production in developing countries. These facilities, which can be built for significantly less cost than traditional plants, offer greater flexibility and can quickly respond to changes in demand.[97]

For decades, the production of mAbs has relied on batch manufacturing, a method where each step—cell culture, harvesting, purification, and formulation—is performed in separate, sequential stages. While this approach has been the industry standard, it comes with inefficiencies: high costs, lengthy processing times, and inconsistent batch-to-batch quality. However, the landscape of mAb production is shifting, with continuous manufacturing (CM) emerging as a more efficient and cost-effective alternative.

Continuous manufacturing integrates the entire production process into a seamless, real-time system. Unlike batch processing—where production occurs in discrete steps, often requiring downtime between stages—continuous manufacturing operates without interruption. In this model, cells are continuously cultured, mAbs are harvested in real time, and purification occurs as the product moves through the system. This method eliminates hold times, minimizes waste, and ensures a consistent product quality.

A leading example of CM adoption is Amgen's next-generation biologics manufacturing facility in Singapore. This plant, which uses continuous processing technology, has achieved a 75 percent reduction in facility size[98] and a 50 percent reduction in manufacturing costs compared to conventional batch processes.[99] By integrating automation and real-time monitoring, Amgen has significantly cut down the time required to produce mAbs, allowing faster market entry for life-saving therapies.

Regulatory agencies such as the USFDA and EMA are increasingly encouraging the adoption of CM for biologics, recognizing its potential to improve drug availability and affordability.[100] The FDA Emerging Technology Program has provided guidance to companies transitioning from batch to continuous production, helping to ease regulatory hurdles.[101]

Looking ahead, CM is expected to become the standard for large-scale mAbs production, particularly for high-demand biologics such as oncology drugs and immunotherapies. However, its implementation in developing countries faces several critical challenges. These

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[97] Gareth J. MacDonald, ”Modular Bioprocessing Lines Help Biopharma Cut Costs”, *Genetic Engineering & Biotechnology News*, 31 May 2023. Available from https://www.genengnews.com/insights/modular-bioprocessing-lines-may-help-biopharma-cut-costs/.

[98] Jenna Fink, ”To Cut Production Costs, Pharma Is Rethinking the Factory, Not the Formula”, *The Signal*, 13 May 2025. Available from https://zero100.com/to-cut-production-costs-pharma-is-rethinking-the-factory-not-the-formula/

[99] Eric Palmer, ”Amgen opens $200M continuous purification plant in Singapore”, *FiercePharma*, 20 November 2014. Available from https://www.fiercepharma.com/supply-chain/amgen-opens-200m-continuous-purification-plant-singapore.

[100] Adam C. Fisher, et al., ”An audit of pharmaceutical continuous manufacturing regulatory submissions and outcomes in the US”, *International Journal of Pharmaceutics*, vol. 622, 2022, p. 121778. Available from https://www.sciencedirect.com/science/article/pii/S0378517322003337?dgcid=author.

[101] Ahmad Almaya and Kim Boue, ”Regulatory Aspects of Global Acceptance of Continuous Manufacturing”, *Pharmaceutical Engineering*, July/August 2021. Available from https://ispe.org/pharmaceutical-engineering/july-august-2021/regulatory-aspects-global-acceptance-continuous.

barriers range from high capital investment[102] and lack of technical expertise[103] to regulatory constraints and supply chain limitations. Addressing these challenges is crucial for making CM a viable option for mAb production in developing countries.

[102] Indu Bhushan, "Demystifying pharma science: batch v/s continuous manufacturing – choosing the right approach", *Express Pharma,* 1 June 2024. Available from https://www.expresspharma.in/demystifying-pharma-science-batch-v-s-continuous-manufacturing-choosing-the-right-approach/#:~:text=Initial%20Investment:%20The%20initial%20investment%20required%20to,the%20installation%20of%20specialised%20equipment%20and%20infrastructure.

[103] Dr. Reddy's, Continuous Manufacturing Process and Its Impact on Pharma Manufacturing. Available from https://api.drreddys.com/articles/continuous-manufacturing-process-and-its-impact-pharma-manufacturing#:~:text=Operating%20a%20continuous%20manufacturing%20system%20demands%20a,the%20smooth%20operation%20of%20these%20advanced%20systems.

VIII. POLICY RECOMMENDATIONS FOR EXPANDING MABS ACCESS

Expanding access to mAbs in developing countries requires targeted policy interventions to address affordability, regulatory barriers, and intellectual property constraints. Governments must prioritize public investment in R&D, improve regulatory efficiency, and implement market-shaping strategies to reduce prices. Strengthening intellectual property policies to prevent unwarranted patent protections and ensuring international cooperation on technology transfer are also essential components of a sustainable access framework.

Increasing public investment in mAb research and local manufacturing is critical to reducing reliance on high-cost imports. Governments should allocate funding to support the development of biosimilars and facilitate public-private partnerships that enhance domestic production capabilities. Additionally, establishing regional manufacturing hubs through collaborative initiatives can improve supply chain resilience and affordability.

Regulatory pathways for mAbs, particularly for biosimilars, must also be strengthened. Developing countries should align their approval processes with the WHO SBP guidelines to streamline biosimilar approvals and eliminate unnecessary and cost intensive animal studies and comparative clinical trials. Expanding reliance-based regulatory frameworks, such as the WHO-Listed Authority system, supported by ensuring access to the full dossier information of the reference regulatory laboratory, can further reduce duplication and accelerate market entry for mAbs.

Intellectual property policies must be revised to prevent undue extensions of patent protection that delay biosimilar competition. Patent offices should apply rigorous examination criteria to prevent evergreening by developing examination guidelines on mAbs, while TRIPS flexibilities—including compulsory licensing—should be actively utilized where necessary to improve access. In addition, facilitating regulatory dossier-sharing among agencies, including sharing of cell lines can enhance transparency, reduce costs and approval timelines.

Finally, international collaboration is essential to fostering equitable access. High-income countries and global health organizations, coordinated by WHO, should support technology transfer initiatives that empower developing countries to build their own mAb production capacity. Encouraging cooperative agreements between regulatory authorities and industry stakeholders for sharing of cell lines and know-how of the manufacturing process can ensure that mAbs reach those who need them most.

By implementing these policy measures, developing countries can overcome existing barriers and establish a more sustainable, equitable, and affordable mAb market that meets the urgent needs of patients worldwide.

IX. Conclusion

Ensuring broader access to monoclonal antibodies in developing countries requires urgent and decisive policy action. While these biologics offer transformative potential in treating a range of diseases, they remain unaffordable and largely unavailable to patients in low-income regions. The primary barriers—high production costs, intellectual property restrictions, and regulatory inefficiencies—must be addressed through strategic interventions.

A critical step forward is to follow a more science and evidence based streamlined approach for biosimilar approval. National Regulatory Authorities (NRAs) should place more reliance on structural and functional analytical data rather than requiring unnecessary animal studies and comparative clinical trials, which have historically increased costs and delayed biosimilar market entry. By adopting these revised standards, NRAs can reduce the financial burden on biosimilar manufacturers while ensuring the safety and efficacy of approved products.

At the same time, reforming intellectual property policies is necessary to prevent extended monopolies that restrict biosimilar competition. Patent offices must enforce rigorous examination criteria to prevent evergreening practices, aided by clear classification of biologic related patent claims and guidelines for the examination of patent claims on mAbs, while governments should actively utilize TRIPS flexibilities, including compulsory licensing, when necessary to safeguard public health.

In addition, public-sector investment in mAb research and local manufacturing must be expanded to reduce dependency on high-cost imports. Countries such as India, Brazil, and Argentina have demonstrated that local biomanufacturing can significantly lower costs and improve supply security. Encouraging further technology transfer and capacity-building initiatives will be crucial for scaling up sustainable production.

Ultimately, achieving equitable access to mAbs requires a commitment to regulatory reform, intellectual property policies that support competition, and sustained investment in domestic manufacturing. The widespread adoption of the 2022 WHO SBP Guidelines presents an immediate opportunity to transform biosimilar accessibility, making high-quality mAb treatments more affordable and widely available in developing countries. Addressing these challenges through coordinated policy efforts will ensure that mAbs reach the patients who need them most, closing the gap in global health equity.

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