

ADVANCED THERAPIES SERIES 1X01

DECODING CAR-T ACCESS: PATENTS
AND LESSONS FROM GLOBAL HEALTH.
WEBINAR READOUT



1. EXECUTIVE SUMMARY

Advanced therapy medicinal products (ATMPs) represent a new paradigm in medical innovation, with the potential to improve the lives of millions of patients globally. However, they are rapidly becoming the site of familiar access failures. Unaffordable prices, promoted by patenting strategies that also create barriers to share knowledge and technology. Finally, lack of governance structures and institutions at international level that impede treating lack of access to these therapies as a global health challenge.

The first session of the Advanced Therapies Series discussed these issues through the presentations of three complementary panelists: Adrián Alonso Ruiz (Salud por Derecho) made the case for treating ATMPs as a global health issue, given the triple burden of extreme global unaffordability, geographic concentration of research and patent ownership, and absent global health governance. José Daniel Rengifo Martínez (Universidad Nacional de Colombia) presented empirical research on CAR-T patent applications in Colombia, showing how intellectual property flexibilities remain available, despite being underused. Giulia Segafredo (Medicines Patent Pool) showed how voluntary licensing has already delivered measurable impact for HIV, hepatitis C, and cancer medicines, while frankly exploring the additional complexity these models face when applied to biologics and cell-based therapies.

Three findings carry particular weight.

- The access crisis for ATMPs is a present reality: treatments priced between \$300,000 and \$2.8 million per patient are unaffordable across virtually all health systems.
- Intellectual property remains a critical lever to block or enhance access to knowledge, technology and medicines. The flexibilities that could limit the patent scope of CAR-T therapies exist in numerous national and regional legal frameworks, but their value depends on consistent and rigorous application.
- Proven access models could be extended to advanced therapies, but doing so requires confronting the added complexity of living-cell manufacturing, hospital-based production pathways, and knowledge-intensive technology transfer that distinguish ATMPs from any previous category of medicine.

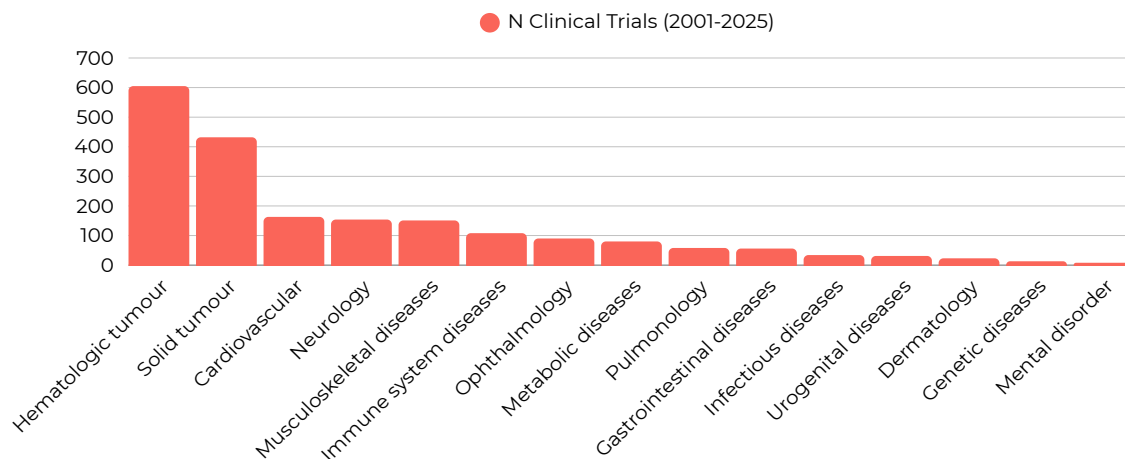


2. ACCESS TO ATMPs AS A GLOBAL HEALTH CHALLENGE

The case that access to advanced therapies is a global health issue remains underexplored., with questions on innovation governance — who can produce these therapies, who can access them, who holds the knowledge — receiving far less attention than other technological or therapeutic areas in Global Health. Three reasons justify the need to incorporate these technologies to global access discussions:



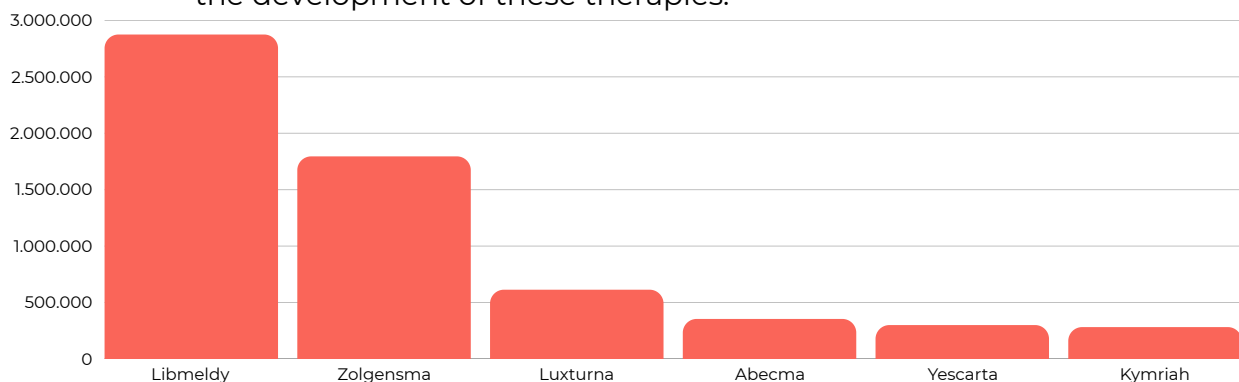
ATMPs encompass a broad and versatile range of platforms with relevance across conditions disproportionately affecting low- and middle-income countries, from infectious diseases to cardiovascular conditions to rare genetic disorders.



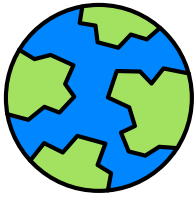
Michiel Vanhaeren et al. *Advanced therapy medicinal products are coming of age: A pipeline analysis of the clinical trial landscape.* <https://doi.org/10.1016/j.drudis.2025.104459>



The prices of approved ATMPs are beyond the reach of most health systems in the world. Libmeldy, a gene therapy approved in Europe, carries a price approaching \$2.8 million per patient. These prices reflect a disconnect between public health and corporate priorities, and an unequal distribution of risks and rewards across the different actors in the development of these therapies.

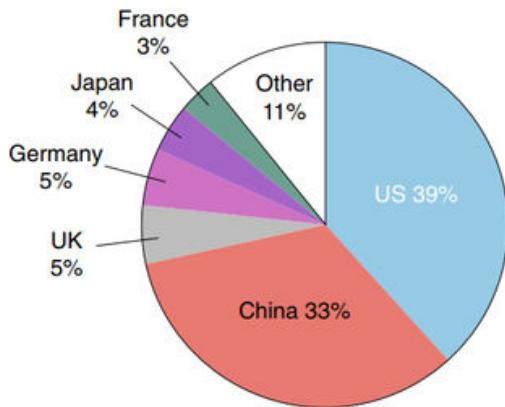


Georgina C. Wilkins et al. *A pipeline analysis of advanced therapy medicinal products.* <https://doi.org/10.1016/j.drudis.2023.103549>



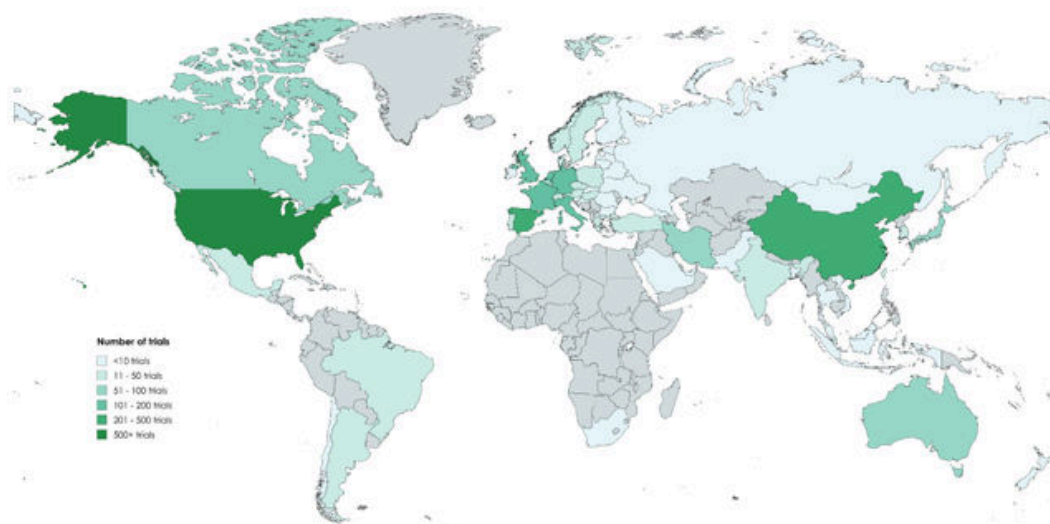
Clinical trials and patent approvals for ATMPs are overwhelmingly concentrated in a handful of countries, with the United States and China accounting for the largest shares. Africa and Latin America are nearly absent from the map of ATMP development. This concentration of knowledge and technology entrenches existing inequities, without institutions and frameworks designed with global equity as a primary objective.

COUNTRY OF RESIDENCE OF CAR T-CELL PATENT APPLICANTS



Jürgens, B., Clarke, N.S. Evolution of CAR T-cell immunotherapy in terms of patenting activity. *Nat Biotechnol* 37, 370-375 (2019). <https://doi.org/10.1038/s41587-019-0083-5>

GEOGRAPHIC DISTRIBUTION OF ATMP CLINICAL TRIALS



Michiel Vanhaeren et al. Advanced therapy medicinal products are coming of age: A pipeline analysis of the clinical trial landscape. *Drug Discovery Today*, Vol 30, Issue 10, 2025, 104459. ISSN 1359-6446. <https://doi.org/10.1016/j.drudis.2025.104459>



Last but not least, technological governance. There are no international frameworks specifically designed to govern ATMP access, technology transfer, or pricing with equity as a primary objective. The regulatory and intellectual property landscapes are complex, and rapidly evolving. These are not technical gaps awaiting technical solutions — they are political absences that require political responses.

3. LOOPHOLES IN PATENTABILITY EXEMPTIONS. EXPERIENCES FROM COLOMBIA

The intellectual property landscape for CAR-T therapies is among the most complex in pharmaceutical innovation. Patent protection has been sought across every component of the technology — from chimeric antigen receptor constructs and viral vectors for gene delivery, to manufacturing processes for cell expansion and clinical methods of administration. By 2019, patent filings had been made across more than 400 patent families in the United States alone, with similarly large numbers through the European Patent Office, the World Intellectual Property Organization's PCT system, and in China. The top ten filing jurisdictions are primarily high-income countries, with Mexico being the only middle-income country to appear among them.

For countries outside the principal patent-filing jurisdictions — particularly in Latin America, Africa, and South Asia — this density of patent protection creates a 'freedom to operate' problem. Developing or adapting CAR-T therapies locally requires navigating a landscape in which nearly every technical step may be covered by a patent owned by a US or European institution, without any voluntary access pathway having been agreed. The question examined at the webinar is whether national patent law flexibilities can provide a remedy.

Research conducted at the Universidad Nacional de Colombia examined this question empirically. A systematic analysis of CAR-T-related patent applications filed with Colombia's Superintendence of Industry and Commerce (SIC) identified 38 national patent files, with the University of Pennsylvania (10 applications), Novartis AG (8), and Kite Pharma (6) among the leading applicants. Thirteen patents had been granted, 19 were under substantive examination, five had been rejected, and one was abandoned. The pattern of claim language across the 38 files was telling: 31 applications used the term 'cells,' 29 used 'methods,' and 25 used 'vectors' — reflecting an attempt to patent not only the biological substances but the processes of their preparation and therapeutic administration.

This matters because international and regional intellectual property law contains an explicit and widely recognised flexibility for exactly this type of claim. The TRIPS Agreement, and the Andean Community's Decisión 486 that governs IP in Colombia, Ecuador, Bolivia, and Peru, allows member states to exclude from patentability 'methods for the treatment of the human body.' The legal logic is well established: therapeutic methods aim to cure disease rather than produce goods for industrial application, and excluding them from patent protection prevents physicians and institutions from being blocked from using established treatment approaches.

Colombia's patent office applied this logic. In 19 of 24 fully examined CAR-T files, examiners raised patentability objections under Article 20(d) of Decisión 486 on the grounds that the claims described therapeutic treatment methods. Methods for infusing modified T cells, methods for providing anti-tumour immunity by cell administration — all were correctly identified as falling within the exclusion. So far, the flexibility was working as intended.

In 12 of the 19 files where objections were raised, applicants made substantial changes to their claims — and in 70.6% of those cases, the changes were sufficient to secure the patent. The mechanism was consistent: following the examiner's objections, applicants rewrote claims to refer to in vitro cell manufacturing methods rather than methods of therapeutic treatment. Rather than claiming 'a method of treating cancer by infusing modified T cells,' they claimed 'a method of manufacturing cells comprising transducing immune effector cells with vectors.'

The description chapters of the same patents — which examiners are required by law to read alongside the claims — made explicit that the cells manufactured by these in vitro processes would be re-administered to human patients for therapeutic purposes. The in vitro manufacturing step and the therapeutic infusion are, in clinical practice, inseparable stages of a single treatment protocol. Yet their legal separation allowed the patent to proceed. In some cases, examination records suggest that the patent office itself recommended the reformulation — effectively coaching applicants to circumvent the very objection it had raised.

The same dynamic is likely to occur wherever patent offices apply the therapeutic methods exclusion without clear guidance on how to evaluate claims whose therapeutic character is embedded in a process that spans in vitro and in vivo stages. Without explicit guidelines, individual examiners face legal uncertainty, and patent applicants — supported by experienced patent counsel — can exploit it.

Two regulatory interventions were proposed. First, Patent Examination Guidelines should be amended to exclude from patentability all methods that include at least one step carried out in the human body, regardless of whether other steps are performed ex vivo or in vitro. This aligns with European Patent Office case law — specifically the principle that a method involving material extracted from and ultimately returned to the body cannot be fragmented into a patentable 'manufacturing' component and a non-patentable 'therapeutic' component.

Second, examiners should be explicitly required to interpret claim chapters in light of description chapters, preventing applicants from severing a manufacturing process claim from its stated therapeutic application.

4. VOLUNTARY LICENSING: A PROVEN MODEL AND ITS OPEN QUESTIONS

Intellectual property, knowledge and technology transfer are different sides of the same access problem. Even where a country successfully limits the patentability of a therapeutic method, or uses TRIPS flexibilities to enable local production, it still requires the technical knowledge, infrastructure, and quality systems to actually make the therapy. For complex biopharmaceuticals — and especially for cell-based therapies — this can represent a formidable barrier.

The work of the Medicines Patent Pool (MPP) offers the clearest existing evidence that voluntary licensing and technology transfer can systematically address access barriers across the pharmaceutical sector. Created by Unitaaid in 2010 to negotiate public health-oriented licences for antiretroviral medicines, MPP has progressively expanded to cover HIV, hepatitis C, tuberculosis, COVID-19, and non-communicable diseases including cancer. Its current portfolio of partnerships spans 22 innovators and 93 generic manufacturers and product development partners in 24 countries. Between 2012 and 2024, MPP-licensed products were responsible for 51.19 billion doses of treatment supplied across 148 countries, representing USD 2.3 billion in savings compared to innovator prices. By 2030, the organisation projects 170,000 deaths averted.

The more recent expansion to oncology provides direct proof of concept for advanced disease areas. In 2022, MPP and Novartis signed a licensing agreement for nilotinib, a treatment for chronic myeloid leukaemia. Within three years, four manufacturers had received sub-licences, two obtained FDA approval in 2025, and the generic product had been filed or registered in 20 LMICs — with an average price drop of 81% compared to the innovator price. As Giulia Segafredo observed at the webinar, this demonstrates that access strategies developed primarily for infectious diseases can be extended to cancer medicines with comparable results.

Yet the limitations of the MPP model for cell-based therapies are real and frankly acknowledged. Unlike small molecules or even monoclonal antibodies, autologous CAR-T therapies involve the collection, genetic modification, and reinfusion of each patient's own cells. Each batch is inherently patient-specific. The process cannot be separated from the clinical setting: manufacturing quality, cold-chain logistics, and clinical administration must be integrated. Technology transfer of these capabilities requires not just knowledge and equipment, but hospital infrastructure, quality systems, and trained multidisciplinary personnel that certain settings currently lack.

MPP's preparatory work on biologics and monoclonal antibodies — a significant scope expansion since 2021 — provides some indication of how these challenges might be approached. A feasibility study conducted in 2021–22 found that technology transfer is critical for LMIC manufacturers to enter the biologics market, that manufacturing costs remain a structural floor to affordability, and that an approach combining fill-and-finish manufacturing (for speed) with full technology transfer (for long-term sustainability) may offer the most viable pathway.

6. RECOMMENDATIONS

The webinar identified a set of priority actions across the actors most directly positioned to shape equitable access to advanced therapies.

For patent offices and IP regulatory bodies

- Adopt examination guidelines that exclude from patentability all therapeutic methods which include at least one step carried out in the human body, even where other steps are performed *ex vivo* or *in vitro*. This interpretation is consistent with existing EPO case law.
- Require systematic interpretation of claims in light of description chapters, preventing applicants from severing manufacturing process claims from their explicitly stated therapeutic application.
- Conduct retrospective reviews of granted CAR-T patents, assessing whether therapeutic methods exclusions were consistently applied, and whether corrective action — including patent oppositions — is warranted.

For governments and multilateral bodies

- Integrate ATMPs into global health access agendas and governance frameworks, such as global health strategies (e.g., Spanish global health strategy), and relevant World Health Assembly resolutions, recognising that access problems in this field are already costing lives.
- Support technology and knowledge transfer for advanced therapies, including through hospital-based production models.

For innovators, academic institutions and research funders

- Design access strategies from the earliest stages of ATMP development, including tiered pricing, licensing commitments, and technology transfer provisions as conditions of public research funding.
- Explore voluntary licensing arrangements for ATMP products with similar to MPP's, acknowledging that these will require model adaptation, technical support, and multilateral co-investment to be effective in the cell therapy context.

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