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The Importance of Balanced Intellectual Property Systems for Patients' Access to Medicines: An Analysis

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Access to safe, effective, cost-effective, and quality-assured medicines is fundamental from a patients' perspective. The International Generic and Biosimilar Medicines Association (IGBA) recently released a report highlighting the critical balance between innovation, competition, and timely access to medicines. This article delves into the key findings of IGBA's report, their implications on patient access to medicines and national healthcare budgets, and the IGBA's recommendations for improving the global pharmaceutical landscape.

L'accès à des médicaments sûrs, efficaces, rentables et de qualité garantie est fondamental du point de vue des patients. L'Association internationale des médicaments génériques et biosimilaires (IGBA) *a récemment publié un rapport soulignant l'équilibre critique entre l'innovation, la concurrence et l'accès aux médicaments en temps opportun. Cet article examine les principales conclusions du rapport de l'IGBA, leurs implications sur l'accès des patients aux médicaments et sur les budgets nationaux de santé, ainsi que les recommandations de l'IGBA pour améliorer le paysage pharmaceutique mondial.*

El acceso a medicamentos seguros, eficaces, rentables y de calidad garantizada es fundamental desde la perspectiva de los pacientes. La Asociación Internacional de Medicamentos Genéricos y Biosimilares (IGBA) *ha publicado recientemente un informe en el que destaca el equilibrio crítico entre innovación, competencia y acceso oportuno a los medicamentos. Este artículo profundiza en las principales conclusiones del informe de la IGBA, sus implicaciones para el acceso de los pacientes a los medicamentos y los presupuestos sanitarios nacionales, y las recomendaciones de la IGBA para mejorar el panorama farmacéutico mundial.*

Access to safe, effective, cost-effective, and quality-assured medicines is fundamental from a patients' perspective. Yet, achieving this goal requires more than the development of innovative therapies. It calls for a well-functioning ecosystem, one that fosters healthy competition, underpinned by robust legal frameworks, and an unwavering commitment to fair practices.

In this context, the International Generic and Biosimilar Medicines Association (IGBA) recently released the report *Gaming the System: An overview of originator companies' evergreening strategies used to hinder access to generic and biosimilar products*, highlighting the critical balance between innovation, competition, and timely access to medicines. This article delves into the key findings of IGBA's report, their implications on patient access to medicines and national healthcare budgets, and the IGBA's recommendations for improving the global pharmaceutical landscape.

A cornerstone of well-functioning healthcare systems is the timely access to safe, effective, cost-effective and quality-assured medicines for patients. Achieving this requires collaboration among various stakeholders, including pharmaceutical innovators, generic and biosimilar medicines developers, regulators, healthcare providers, and patients. Each plays a distinct yet complimentary role, and mutual respect among these parties is essential to sustain an inclusive and resilient healthcare ecosystem.

One of the most effective mechanisms for stimulating innovation and ensuring access to medicines is competition. A thriving competitive environment not only allows for the development of innovative therapies but also simultaneously ensures that once patent protections expire, more affordable alternatives become available. This cycle, where innovation is followed by off-patent competition, facilitates affordable access to medicines and exemplifies what is often referred to as a "balanced IP system."

A balanced intellectual property (IP) system is one in which truly innovative therapies are developed and protected by quality patents for a specific, well-defined period, providing innovators with the opportunity to recoup their investment and continue funding further research, and, as soon as these protections end, competition is facilitated by the timely entry of generics and biosimilars, driving down the cost of treatments, broadening access to medicines, and stimulating further innovation. It is a virtuous process.

However, when the protective mechanisms designed to support this succession of events are manipulated or misused, the entire system described above is jeopardized. The report emphasizes that such disruptions lead to legal uncertainty and delay or prevent timely competition, undermining further innovation, investment, and therapy development and ultimately hindering access to medicines for patients.

In this context, the IGBA's report plays a critical role in raising awareness about the consequences of these disruptions and provides a strong foundation to constructively work towards a sustainable, pro-competitive pharmaceutical market.

Key Findings of the Report

IGBA's report provides a comprehensive global overview of practices that delay competition from generic and biosimilar medicines. The findings highlight the detrimental effects of these practices on innovation, patient access, and competition.

One key finding highlights how certain patent-holding companies around the world engage in various strategies designed to extend their monopoly on certain drugs, unduly delaying the introduction of generics or biosimilars. These practices are employed in different regions, affecting both mature markets and emerging economies.

However, the misuse of patents and regulatory systems is not confined to specific countries or regions. The report reveals that no region is immune to the practice of delaying the launch of off-patent medicines. These practices are increasingly evident not only in jurisdictions with sophisticated patent systems, such as the United States and Europe, but also in emerging markets.

The report identifies several patent-related practices that can delay competition, including:

- **Poor Patent Quality:** Weak patent examination processes and the granting of non-innovative patents is the root cause of barriers for generic and biosimilar developers.
- **Patent Thickets:** A proliferation of a myriad of patents covering the same product results in costly and protracted litigation, creating uncertainty for generic and biosimilar companies.
- **Sham Litigation and Patent Linkage Abuse:** These practices pressure regulatory bodies to deny market access to off-patent medicines, even in regions where patent linkage is illegal.

In addition to patent-related issues, non-patent-related strategies, such as **predatory pricing, product hopping, and denigration of generic or biosimilar medicines**, further complicate the competitive landscape. These tactics prevent generic and biosimilar manufacturers from entering the market timely, stifling healthy competition and limiting access to affordable medicines.

In many instances, companies employ multiple strategies simultaneously within the same jurisdiction to further delay competition and maintain monopolistic control over medicines. The report shows that some practices—such as patent linkage, patent thickets, and sham litigation—have been employed across multiple regions for the same products, highlighting the global nature of this challenge.

One example of this, also highlighted in the report, is the case of Trajenta (linagliptin). Here is a direct quote from the Report:

"In relation to Trajenta® (linagliptin) and Trajenta Duo® (linagliptin; metformin), used to treat type 2 diabetes mellitus, the originator company initiated multiple patent infringement lawsuits in India in parallel before two courts in order to block the entry of several generic products. While one court issued preliminary injunctions preventing generic companies from launching until patent expiry, in the parallel case, one year later, the Delhi High Court reached a different outcome and rejected the preliminary injunctions request, stressing that '*by filing multiple patent claims in respect of the same invention, the plaintiffs have made an attempt towards evergreening the invention and re-monopolizing the same. […] The aforesaid conduct of the plaintiffs defeats the rights of the manufacturers of generic drugs such as the defendant companies and is also detrimental towards the public interest.*' Additionally, the court ordered the originator company to compensate the generic companies financially.

As a result of this preliminary injunction strategy, generic companies were prevented from launching affordable and accessible products from February 22, 2022, until March 29, 2023".

Another example is Keytruda® (pembrolizumab) which is a vital but expensive anticancer drug, priced at around USD 165,000 per year. By October 2021, the originator had filed 129 patents in the U.S. to extend its monopoly, echoing the patent thicket strategy used for Humira®, which delayed biosimilar entry by years. With Keytruda® generating USD 25 billion in sales in 2023 and projected to surpass USD 30 billion by 2026, any delay in biosimilar competition could significantly strain the U.S. healthcare system and restrict patient access.

Many similar examples are provided in the report, showing the huge impact of misuses of the system in terms of delayed treatment for patients and of lost savings for healthcare systems.

Decision makers often fail to account for the interplay between regulatory, IP, and market access legal frameworks allowing companies to exploit these gaps. Indeed, this leads to significant delays in market entry for generics and biosimilars, ultimately resulting in billions of dollars in lost savings and preventing timely patient access to treatments.

Most importantly, the above-mentioned practices disproportionately impact patients, particularly those suffering from complex diseases. Delays in the availability of generic or biosimilar treatments prevent patients from accessing affordable alternatives, which, in turn, affects their health outcomes.

The coexistence of two key healthcare objectives—innovation and access—can be continuously disrupted by these inappropriate practices. While innovation is essential for developing new therapies, healthcare systems should allow for a rapid transition to competition in the market.

The report emphasizes that delayed market entry for generic and biosimilar medicines not only hampers competition but also exacerbates the financial strain on healthcare systems. Without competition, prices for essential medicines remain high, burdening healthcare budgets and limiting access to life-saving treatments for patients. Additionally, this delay has a chilling effect on future investment in the development of new medicines, as the lack of competition discourages pharmaceutical companies from investing in new products.

Furthermore, the absence of competition in the off-patent medicines sector ultimately undermines the long-term sustainability of healthcare systems worldwide. For instance, countries with limited access to affordable medicines often face increased healthcare costs, which can strain public health systems and reduce their ability to invest in other essential healthcare services.

Recommendations for Mitigating the Challenge

The IGBA's Report proposes a series of key recommendations to mitigate the negative impact of these practices and restore balance to the pharmaceutical market:

1. **Contribution of the Off-Patent Medicine Sector:**
   - All stakeholders must acknowledge that a thriving off-patent medicine sector is an integral, fundamental part of the broader pharmaceutical innovation ecosystem. Generic and biosimilar medicines contribute significantly to improving access and reducing healthcare costs.

2. **Enhanced Collaboration Across Stakeholders:**
   - There is a call for increased collaboration among competition authorities, patent offices, and health authorities to exchange information on practices that lead to delays in competition. This collaboration is essential for fostering a more transparent, equitable and effective pharmaceutical market.

3. **Improvement of Regulatory and IP Frameworks:**
   - To prevent the misuse of patents and regulatory systems, IP, regulatory and market access rules should be designed with careful consideration of their potential interactions. This holistic approach would help prevent potential loopholes that dominant companies may exploit to delay the entry of generics and biosimilars. To this end, it is important to empower competition authorities to play an active role in policy making processes.

4. **Ensuring Quality Patents in Achieving Balanced IP Systems:**
   - Patents are intended to serve as a reward for genuine innovation, providing with exclusive rights that encourage research and development. However, when patents are misused to block competition, the integrity of the system is undermined and its balance is lost.Strengthening safeguards within the patent examination process to ensure that only high-quality, meritorious patents are granted is essential. This is a critical step toward preventing abuse and ensuring that the system continues to promote and protect true innovation.

5. **Strengthening Patent Offices and Competition Agencies:**
   - There should be multi-stakeholder advocacy for robust patent offices that grant quality patents to protect genuine pharmaceutical innovations. Additionally, regulatory bodies must be proactive in identifying anticompetitive practices and taking swift action when necessary.

6. **Proactive Policy Review:**
   - Policy frameworks should undergo regular reviews to address any loopholes that may allow delays in competition. Adaptations to these frameworks should ensure that guardrails supporting innovation and timely access are well-implemented and remain effective in the changing landscape of global medicine.

In conclusion, IGBA's report provides a critical examination of the practices and strategies that undermine competition in the off-patent medicines market. The findings highlight the far-reaching consequences of monopolistic tactics, delaying patient access to affordable treatments, inflating healthcare costs for national systems, and diminishing incentives for future innovation. Addressing these challenges requires comprehensive reform across regulatory, patent, and market access legal frameworks, stronger global collaboration among stakeholders, and more robust measures to prevent and enforce against anticompetitive practices. By addressing these issues, the pharmaceutical industry can help restore the delicate balance between innovation and access, ensuring that the benefits of advances in modern medicine are shared by all patients.

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This article is based on the IGBA report "Gaming the System: An overview of originator companies' evergreening strategies used to hinder access to generic and biosimilar products" (2025).

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