

*COUNTRIES THAT WANT
TO BUILD AN INNOVATION-
DRIVEN KNOWLEDGE
ECONOMY SHOULD EMBRACE
PATENT LINKAGE*



THE PROMISE OF PATENT LINKAGE

■ By Jack Ellis, Geneva Network

- Patent linkage creates efficiencies for drug regulators and patent offices by connecting the approval and validity processes
- It benefits both pharmaceutical originators and generic/biosimilar manufacturers by clarifying the status of patents relevant to new drug products
- It provides certainty for pharmaceutical innovators, helping ensure their commitment to future investment in drug development
- It also gives generic/biosimilar drug manufacturers the necessary information to contest the validity of questionable originator patents while deterring them from challenging valid patents, allowing them to allocate resources more efficiently
- Patent linkage encourages further investment in research and development in the generics/biosimilars sector, moving it further up the value chain
- Despite claims of US self-interest in imposing patent linkage through free trade agreements, several jurisdictions have introduced such systems independently to bolster their domestic life sciences industries and promote foreign investment

Robust intellectual property (IP) protection is vital for biopharmaceutical innovation. It provides the incentives and business certainty needed to attract and sustain long-term investment in prevention, treatments and cures. IP rights have little value without enforcement, however.

Trademark infringements by counterfeit medicines are common and well understood, and high on the public and policymakers' radar screen. Other forms of IP rights abrogation are less visible but no less corrosive to the delicate innovation ecosystem.

In many countries, for instance, drug regulatory authorities are not required to - and do not - notify innovators when competitors apply for approval to market a generic version of a medicine or vaccine.

This often leads to the marketing

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of generic medicines while the patent of its corresponding originator medicine is still in place, in effect reducing its value to zero and undermining the very rationale of protecting IP in the first place. Unsure of the effectiveness of local IP rights protection, foreign and local investment looks elsewhere.

For forward-looking nations keen to develop their own innovative biopharmaceutical industries, this state of affairs is increasingly untenable. In response, the last decade has seen more countries introducing into their domestic legislation early resolution mechanisms for patent disputes, which clarify the link between the patent status of medicines and the regulatory approval of generic equivalents. The objective of such legislation is to promote innovation and investment by giving inventors more certainty over their patent rights, while giving generic manufacturers greater clarity over their freedom to operate in the marketplace.

■ TAIWAN LOOKS FOR LIFE SCIENCE GROWTH

One jurisdiction at the vanguard of this new policy push is Chinese Taipei (Taiwan), an advanced, high-income economy, with per capita GDP of US\$46,783 as of 2015, ranking alongside Germany and Iceland, according to the

International Monetary Fund. This status was achieved in the post-Second World War period through market liberalisation and a focus on mass production, and the island remains one of the world's foremost manufacturing hubs.

Sceptics would likely argue that Taipei is under pressure from larger trade partners and the pharmaceutical originator industry to reform its laws surrounding the early resolution of patent disputes. But a closer look at the island's particular economic circumstances, and the linkage rationale itself, may suggest otherwise.

Recently Taiwan's substantial manufacturing sector has faced increasingly stiff competition from emerging markets, particularly from near-neighbours in South East Asia and mainland China. Downstream businesses such as electronics components and product assembly, once the island's bread-and-butter, have been losing out for years to competitors that can often provide the same contract manufacturing services at substantially lower prices.

Contending with this reality, the Taiwanese authorities are looking to encourage higher value-added, innovation-intensive industries to secure future growth. And the life sciences are one place where they are pinning their hopes. The island's government recognised the potential for growth in

these sectors in the 1980s, and has taken a proactive approach towards encouraging investment in R&D, manufacturing and production capacities, according to a 2007 report from Chei-Hsiang Chen of Taiwan's Ministry of Economic Affairs. In 1995, the island launched its biotechnology industry Promotion Plan with the aim of becoming the Asia-Pacific region's main centre for clinical trials, genomic research and biotech-focused venture capital.

Today, it would appear that these efforts are beginning to bear fruit. According to 2015 research from PricewaterhouseCoopers, Taiwanese pharmaceutical companies made US\$2.8 billion in 2013. But this figure doesn't tell the whole story; the lion's share of this income is accounted for by generic production, rather than higher-value innovative drug development.

Generic drug production, while useful, can't offer the long-term economic impact of drug innovation. It is a business of razor-thin margins, and essentially involves the replication of products that have been invented, designed and manufactured elsewhere. As such, it does not generate the longer-term economic value, tax revenues and attractive, high-value jobs that R&D-intensive originator companies can.

■ ROUTINE PATENT INFRINGEMENTS BY GENERIC MANUFACTURERS

Despite the Taipei authorities' efforts towards developing its life sciences industry, the island is still failing to attract significant buy-in from prospective investors, including foreign biopharmaceutical companies.

A December 2015 report on the Taiwanese market from IHS Markit states: "Challenges in IP rights policies persist, deterring multinational companies from investing in the sector.... One major issue is that many patent-infringing drugs are being approved and included in the reimbursement list."¹

An industry survey conducted by the International Research-Based Pharmaceutical Manufacturers Association (IRPMA) - which represents over 40 drugmakers from Europe, Japan, and the United States operating in Taiwan - found that at least 65 patent-infringing drugs had been approved by the island's authorities, most of which were subsequently included on the reimbursement lists (i.e., the lists of products available to healthcare professionals for prescription to patients).

This widespread infringement of

"The Taiwanese authorities are looking to encourage higher value-added, innovation-intensive industries to secure future growth"

¹ <http://blog.ihs.com/taiwan%E2%80%99s-pharmaceutical-market,-as-it-is-preparing-to-join-tpp-in-the-second-round>

WHAT IS A PATENT?

- A patent is an exclusive right granted for an invention, which is a product or process that provides a new way of doing something or offers a new technical solution to a problem.
- In exchange for disclosing a detailed description of an invention, a patentee may prevent others from making, using, distributing, selling or importing a protected invention for a limited time.
- Patents are temporary. They protect inventions for a limited period of time, typically 20 years from the date a patent application is filed.
- Patents are granted by national or regional patent offices and applicable only in those jurisdictions. Firms doing business worldwide must secure patents in multiple countries.

Source: WIPO, USPTO

the intellectual property rights of originators impacts their earnings by introducing generic competition earlier than the patent system intends.

It also sends out a broader signal that the rule of law is weaker in Taiwan than in other comparable jurisdictions, with the authorities prepared to turn a blind eye to the infringement of intellectual property rights. This impacts investment not just in pharmaceuticals and biotechnology, but in other sectors, too.

“Sufficient freedom, concrete regulations and just law enforcement are all cornerstones supporting steady economic development,” says Peng-Yu Wang, general director of technology transfer at the Industrial

Technology Research Institute (ITRI), Taiwan’s publicly funded R&D organisation.

“To attract continuous investment and foster constant technical developments and improvements, researchers and innovators should receive fair remuneration.” It is expected profits, after all, that incentivise pharmaceutical originators to invest in the continued development of new drugs.

The exclusivity afforded by patent protection is one of the main ways in which originators can safeguard their ability to turn those profits. But the commonplace entry of infringing generic products onto the Taiwanese market, as suggested by the IRPMA findings, renders the remaining term of the originators’ patents worthless.

“If the patent is still valid and has not yet expired, it is reasonable to keep the generic drug from the market,” says Wade Lin, a patent attorney with Taipei-based Formosa Transnational. “If we let the generic drug erode the profit that the brand name drug companies deserve by letting it infringe the patent right, the incentive for new drug development will eventually disappear.”

Crucially, this not only diminishes investment in new drug innovation, but ultimately destroys the viability of the generics’ business model too, he adds.

“Without the brand name drugs, the generic drug companies would also not be able to survive.” The whole industry then comes crashing

down, he says. “So if that happens, then what about the patients in need? What about the economy? We have to realise that we are actually all in the same boat.”

■ EARLY RESOLUTION MECHANISM FOR PATENT DISPUTES

The Taiwanese authorities have realised that allowing the routine infringement of IP rights by generic manufacturers is not good for the long-term future of the economy. To address this, Taiwan is one of several jurisdictions implementing an early resolution mechanism to reduce the numbers of generic drugs gaining marketing approval before the originator patent has expired.

The plan, designed by Taiwan’s Ministry of Health and Welfare, with support from the Taiwan IP Office, would link the patent status of a medicine and regulatory approval of a generic, preventing the latter from gaining regulatory approval while the patent on the original version is still valid.

At a basic level, linking these two elements means that generic versions cannot gain regulatory approval while the patent on the original version is still valid. The aim is to protect the IP rights and investment of the original innovator, while allowing the generic manufacturer to avoid

becoming embroiled in costly legal disputes.

While different government agencies are responsible for the entirely separate processes of granting patents for new medicines and for approving new pharmaceutical products for market entry, too often regulators will grant marketing approval for a generic without regard to whether an applicable patent remains in force.

Effective early resolution mechanisms have three major features.

First, a mechanism for ensuring that innovators list relevant patent information in one common location, such as an online database. This listing enables manufacturers to have knowledge of the patents identified by an innovator that could affect subsequent marketing applications. Based on this information, other manufacturers can decide whether to wait for the relevant patents to expire before obtaining marketing authorisation or to challenge the patent(s) on the original medicine.

Second, sufficient mechanisms for requiring notice to key stakeholders (manufacturers and government entities) regarding potential patent disputes brought about by generic or biosimilar marketing applications. This notice can include the listing

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“For generic manufacturers such a mechanism enhances predictability and transparency around the regulatory approval process, by highlighting third-party patents that could prove an impediment to a generic company’s business strategy”

of an application for a drug in a publicly available resource, such as an online database, or the direct giving of notice to the innovator or regulatory authority.

Third, there must be opportunities for manufacturers to use legal means to resolve patent disputes early. Patent disputes are ideally resolved prior to marketing of a generic or biosimilar in order to provide business certainty and stability in the marketplace for all participants.

■ EXPENSIVE LITIGATION

Litigation brought about by the premature market entry of a generic medicine, or the challenging of an existing patent by a generic manufacturer, are expensive and lengthy processes that are not undertaken lightly by either party. Early dispute resolution mechanisms such as patent linkage ensure any litigation takes place earlier, therefore giving the originator a fair opportunity to secure a return on its long-term, high-risk investments in research and development, which can run into billions of dollars for some of the latest biologic treatments. Crucially, this helps to incentivise future investment in innovative drug development.

■ WIN WIN

For generic manufacturers too, such a mechanism can give competitive advantages and assist them in avoiding infringement. It enhances predictability and transparency around the regulatory approval process by highlighting third-party patents that could prove an impediment to a generic company’s business strategy. This means that the generic manufacturer can reduce risk and allocate resources to products less likely to be halted by litigation, thereby creating efficiencies that impact positively on its bottom line.

Moreover, under the US system - and similar schemes in the Republic of Korea and the proposed regime in Taiwan - generic companies are incentivised to challenge patents they suspect of being invalid, as the first to file a successful invalidation action is granted a period of market exclusivity to sell their generic version of the drug. This in turn encourages innovator companies to ensure that the patents they file are of a high quality.

Finally, patients also benefit as they no longer run the risk of having to switch back and forth between different treatments that could have different side-effects and efficacy depending on the outcome of IP battles between innovators and generics.

■ PATENT LINKAGE AROUND THE WORLD

Taiwan is not alone in recognising the long-term damage caused to innovation and economic competitiveness caused by allowing patent infringing medicines to be made publicly available. Increasingly, early resolution mechanisms are becoming a global standard in the protection of IP rights.

The United States introduced an early resolution mechanism for patent disputes with the passage of 1984's Drug Price Competition and Patent Term Restoration Act (otherwise known as the Hatch-Waxman Act after the two US Congressmen who sponsored the bill). Under the US system, the country's Food and Drug Administration (FDA) lists patents belonging to originator companies: manufacturers that seek marketing approval for generic versions must notify the rights-holding company that it is doing so. Northern neighbour Canada has a similar system.

Other countries entering into Free Trade Agreements (FTAs) with the United States have also upgraded (or plan to upgrade) their IP systems to provide some form of early resolution mechanism. According to a March 2013 paper by Ravikant Bhardwaj, K D Raju and M Padmavati of the

Indian Institutes of Technology Kharagpur, in 2011 alone no fewer than 16 nations had FTAs with the United States which required them, explicitly or implicitly, to provide early dispute resolution mechanisms, including Australia, Korea and Singapore².

Although its future now looks uncertain, the planned Trans-Pacific Partnership (TPP) also requires signatory states to implement early resolution mechanisms for patent disputes - from Asia, this would include Malaysia, Brunei and Vietnam.

However, the rise of patent linkage as an increasing norm in Asia is far from dependent on US trade policy. Several FTAs to which the United States is not a party - such as those between Colombia and Mexico, and Japan and Thailand - include provisions for early resolution mechanisms³.

Add Taiwan to this mix, and it becomes clear that early resolution mechanisms for patent disputes are emerging as a regional standard in Asia.

■ ENCOURAGING INNOVATION IN THE GENERIC DRUG INDUSTRY

Back on the island, the generic manufacturers that currently

"... early resolution mechanisms for patent disputes are emerging as a regional standard in Asia"

² [http://nopr.niscair.res.in/bitstream/123456789/20282/1/JIPR%2018\(4\)%20316-322.pdf](http://nopr.niscair.res.in/bitstream/123456789/20282/1/JIPR%2018(4)%20316-322.pdf)

³ https://www.wto.org/english/tratop_e/trips_e/trilatweb_e/ch4c_trilat_web_13_e.htm

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comprise the backbone of the pharmaceutical industry are expressing their worries about the arrival of an early resolution mechanism for patent disputes. From their perspective, this would put more power into the hands of originator companies, thereby keeping their cut-price copies off the market for longer. Is their anxiety justified?

“They have concerns that brand name drug manufacturers might register irrelevant patents, or patents with low quality, to the database of approved drugs,” patent attorney Wade Lin explains. “They also worry that patent litigation would be initiated earlier than before and might take a long time to solve, delaying the time of the drug to market.” The further worry is that this situation would potentially increase the cost burden on public health systems, forcing them to continue paying premium prices for patent-protected, originator-brand drugs.

But, as already mentioned, patent linkage systems can introduce added certainty into the drugs market for generic manufacturers. “The applicant for a generic drug licence is informed of any patents relating to their product before it launches,” says Lin. The listing of on-patent medicines allows follow-on drug makers to navigate the competitive landscape to avoid infringement - and to direct their validity challenges more precisely and efficiently should they see an

opportunity to do so.

Moreover, this ability to understand the relevant patent landscape prior to market entry encourages generic manufacturers to innovate themselves, moving the entire generic industry up the value chain. “In addition, the generic manufacturer can also be urged to engage in R&D or design-around efforts, encouraging innovation in the generic drug industry,” Lin adds. “Ultimately, that enhances the industrial strength and international competitiveness of Taiwan.”

The knock-on effect of more R&D activity in both originator and generic camps would also lead to the development of ancillary services and increase opportunities for foreign investors, he adds.

It would be imprudent to think that patent linkage can solve perceived problems with drug pricing and healthcare delivery. What it can help to achieve, however, is a pharmaceutical innovation ecosystem where innovators are fairly rewarded for their R&D investments and where generic drugs can enter the market in a less risky and more efficient manner.

■ A NEW GLOBAL IP STANDARD

While the originator and generic pharmaceutical industries are portrayed as at loggerheads,

they are, in fact, symbiotic. Generic manufacturers would not have a viable business model without the investments made in research and development by originators; the competitive challenge presented by the expiry of patents and generic entry keeps the originators on their toes, encouraging them to continue innovating and creating new drugs.

When the two sides do come into conflict, it is usually because an originator suspects that generic competitor has infringed

one of its patents. Intellectual property disputes of this type are expensive and time consuming, and sap resources that could be better spent on further research and development.

Early resolution mechanisms for patent disputes aim to bring efficiency and clarity to this situation. Moreover, an environment where patent owners feel confident that their IP rights are respected and enforceable is one in which they will be more comfortable investing. That in turn drives

knowledge-based economic development - and demonstrates why countries pursuing growth should embrace patent linkage, rather than reject it.

If Taiwan passes legislation in this area, the country will be joining other regional powerhouses with similar laws on their books such as Korea and Singapore. Rather than seeing itself as an outlier, Taiwan should be confident that it is implementing a new regional standard for the protection of intellectual property.



ABOUT THE AUTHOR

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Previously, Jack was the Asia-Pacific editor of *Intellectual Asset Management* magazine. He has also worked in a number of editorial and research roles covering intellectual property, the legal services market and the non-profit civic sector.