

The IP Law Book Review

IP Law Center, Golden Gate University School of Law

Vol. 3 No. 1 (November 2012) pp. 24-29

IMITATION TO INNOVATION IN CHINA: THE ROLE OF PATENTS IN BIOTECHNOLOGY AND PHARMACEUTICAL INDUSTRIES, by **Yahong Li**. Edward Elgar, 2010. 189 pp. Hardback \$112

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IMITATION TO INNOVATION IN CHINA heralds a new generation of English monographs that examines the Chinese intellectual property regime for its own sake. Yahong Li delves into the challenges of innovation and patent protection in China's rapidly evolving biotechnology sector, and those who join her foray are rewarded with a new appreciation of how the patent system relates to its traditional promise of spurring innovation. Her study of China's patent system avoids the narratives of counterfeit and piracy that came to dominate so much of the writing on Chinese IP protection in the last decade.

This reorientation could not have come too soon. Even as of 2011, the Chinese IP headlines that captured public attention worldwide were the case of the fake Apple Store in the city of Kunming and the alleged misappropriation of high speed rail technology by the Chinese government. To the extent that China's IP developments are recognized in the legal literature, they are tempered with anxieties about "indigenous innovation" and "junk patents", both negatively connoted. The emphasis is distinctly exogenous and mercantilist—China's IP practices are only interesting, it would seem, to the extent that they are shown to have effects on the West and vice versa. Li's study is refreshing because it examines patent law in light of its original function of promoting domestic welfare.

It is precisely in her frank and relentless investigation of the link between Chinese patent and pharmaceutical innovation that the book finds resonance outside the immediate circle of Chinese IP scholarship. Stripped to its core,

her subject is the relationship between patents and innovation—the perennial debate at the center of the patent field. Those who have read Christine MacLeod’s analysis of the English patent system during the industrial revolution know that in order to understand the strengths and weaknesses of ones’ own system, it is sometimes necessary to observe its operation from the outside and subject it to conditions far from one’s own.¹

This time Li takes us to China, and with higher stakes: her subject is the present, and her audience includes policymakers and entrepreneurs who are in a position to influence economic development and medical welfare in the most populous country in the world.

Chapter one situates the readers in the current split in the literature regarding the role of patents vis-à-vis innovation in developing countries; that is, do patents help or hurt development? (pp.14-16). Chapter two surveys a dense array of statistics characterizing the growth of China’s biotech and pharmaceutical sector, and chapter three enlists detailed case studies showcasing the variation of R&D capacity, collaboration models, and government support across technology subfields. Together, these two descriptive chapters introduce the state of the Chinese biotech and pharmaceutical sector at the start of the century: China is strong in genomics, transgenic organisms, cloning, and biopharmaceuticals but weaker in chemical drug discovery and stem cell research (pp.30-38); a great majority of the support comes from the government, alongside foreign investments and collaborators drawn by China’s market, low cost, talent pool, and R&D infrastructure (pp.42-43).

Chapter four begins the theoretical inquiry with a study of China’s R&D models, which Li divides into four categories from the least to the most innovative: imitation, “me-too” innovation, “me-better” innovation and “me-first” innovation (pp.52-59). For the first category, studies of pervasive copying are duly cited: 97% of synthetic drugs are copies of others products, 99% of all companies involved in anti-cancer drugs produce imitation drugs, generics make up 90% of the biologics drug market (pp.52-53). But on balance, pure copying is no longer a viable business model due to low prices, fierce competition, infringement risk and diminishing returns on further copying since “there are not many new drugs left to be imitated” (p.53). Meanwhile, breakthrough innovations are “practically impossible” for China’s current scientific and financial strength (p.65). The only path left open, she reluctantly acknowledges, is that of incremental innovation based on variations of the existing state of the art, which in turn depends on “sophisticated legal and technical expertise to find the patent loopholes of pioneer inventions ...” (p.65). Chapter five

examines biotech and pharmaceutical patenting trends and further reveals that the better IP assets and stronger patents are still in the hands of multinational corporations, despite increasing patent filings from domestic companies, which in turn leads to increasing patent litigation.

So how should China formulate its patent system to enable an incremental innovation strategy when the sector is dominated by the IP of multinational pharmaceutical corporations? To answer this question, Li examines Chinese patent law as it applies to this sector. She addresses issues of patentable subject matter (Chapter 6), conditions of patentability (Chapter 7) and the treatment of patent rights (Chapter 8). The Chinese government appears to have responded to foreign patents by trimming back protection in the latest round of patent amendments in 2008 (p.169). Li instead prescribes a stronger patent system and more patenting as the solution (pp.157, 161). This central policy claim is based on the balance of the patent's dynamic incentives versus the static welfare loss particular to China.

On the positive side, Li observes substantial prospect interest and signaling effects at work:

...Patents do promote innovation in the biotechnology and pharmaceutical industries to the extent that they boost incentives for investment from domestic private sector and foreign investors, foster an innovative spirit and culture among research institutions, and help to identify national strategic areas for S&T development (p.157).

On the issue of the welfare loss due to a possible patent thicket or limited medical access, she finds the effect less serious than some have assumed. To the former, she notes that "the obstacle for technology access was not caused mainly by patents but rather by the MPC patent holders, who account for about a third of total patent holders in China" (p.177). This obstacle is surmountable because historically MPCs have not obtained extensive patent coverage and now face successful patent challenges. For example, out of eleven Chinese patent applications that were filed for the transgenic "Golden Rice", only two were granted, and even those two were ultimately invalidated (p.170). Moreover, the industry has a successful track record of licensing or inventing around patented technology and Chinese companies can reverse their fortunes by patenting more innovations of their own. On the balance, it is better to maintain strong incentives to promote innovation and let time fix the uneven distribution of patents than to reduce the desire for innovation overall. As for public medical welfare,

she ascribes access problems to the profit motives of hospitals and generics companies themselves rather than to patent exclusivity (p.171).

Scholars of Chinese IP law or technology development will benefit from Li's extensive collection of references and the synthesis of Chinese language materials. These, especially the analysis of legal disputes and government support programs, are rarely in one place and accessible to the English-speaking community, although the majority of the data and cited studies predate 2008 and reflect a historical snapshot from half a decade prior. For example, the study reports that only 15.4 percent of domestic patents were granted for inventions as opposed to utility models or industrial designs in 2008 (p.70). The latest figure from SIPO for 2011 suggests the mix of invention patents has increased to 25.4% a mere three years later, which appears to confirm Li's endorsement of China's technical capacity.² To be sure, all studies have to cut off at some point, and these historical figures represent a testament to the rapid changes going on in China. They also provide a baseline matrix for future comparisons.

Those interested in broader IP and development issues will relate to "the context of China's transitional economy and its place as the world's largest developing country with a relatively high technological capacity" (p.157) but "low capacity in commercialization" (p.161) and draw immediate comparisons to the other BRIC countries facing a similar confluence of foreign patent ownership and domestic needs. Li's approval of a strong patent regime seems to contradict the path taken by other developing countries such as India, Brazil and Thailand, but China is simply at a different point along the trajectory of economic transformation. Whether one agrees with Li's ultimate conclusion that China is ready for a strong patent system, policymakers can look to the technological conditions examined in this study to evaluate when and whether a national patent system should switch from low protection to higher protection.

Developed countries boasting a higher level of innovative capacity may also take heed, notwithstanding Li's prescription targeting "incremental innovation". The division of innovative capacity into pure imitation, "me-too" imitation, "me-better" and pure innovation may be more suited to catalogue inventiveness *ex post* rather than serving as *ex ante* policy guideposts. It can provide a useful descriptive framework to consider the effects of patent law on countries at varying stages of development. But attention to detail is crucial to the categorization project: to illustrate the concept of "me-too" innovation, for example, Li cited Cialis and Levitra as analogues of Viagra, even though these chemical analogues are new chemical entities with improved therapeutic profiles and developed by

recognized innovators like Bayer (p.54). Li also includes in the example of incremental innovation three Chinese-developed cancer treatment products, Gendicine, Oncorine, and Endostar, which are no less than the first, second, and third commercially available gene therapy products anywhere in the world (pp.34, 55). If all that Chinese firms can manage are incremental innovations of such caliber, they would have done very well in terms of profitability, patient welfare, and contribution to the store of knowledge. It is unclear that we would want to provide less of a reward to beneficial improvements merely because they are incremental, nor should we presume to know what policy choice promotes disruptive technology over incremental improvements. Thus, Li's advice for China is equally relevant to countries that have embraced a notion of innovation broader than a "flash of creative genius".³

IMITATION TO INNOVATION IN CHINA is an endorsement of the patent system based on a look from the inside, making it far more credible than a call for higher IP protection during bilateral trade talks. However, the endorsement is clearly situational: the perceived benefits are reserved for those countries having significant technical capacity but relatively fewer blocking patent rights. The ironic lesson of the China case is that the benefits of a stronger patent system may depend on a prior period of lesser protection. Interestingly, this suggests that perhaps there is no optimal national patent system but only an optimal cycle of patent systems that waxes and wanes in counter step to the level of patenting.

¹ Christine MacLeod, *INVENTING THE INDUSTRIAL REVOLUTION: THE ENGLISH PATENT SYSTEM, 1660-1800* (Cambridge University Press, 2002).

² State Intellectual Property Office, "National Patent Application Received Exceeded 1.63 million", available at www.sipo.gov.cn/yw/2011/201201/t20120106_640395.html.

³ *Cuno Engineering Corporation v. Automatic Device Corporation*, 314 U.S. 84 (1941).

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Suggested citation: 3 *The IP Law Book Review* 24 (2012)