

Will Japan Reward Innovation?

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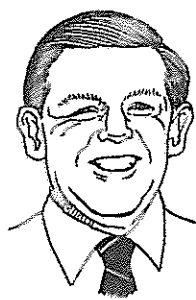
The title of this article raises more than one question, in fact four questions, one for each word:

WILL? Does this mean innovation in Japan was not rewarded in the past?

JAPAN? Does this mean the government? Japanese venture capitalists? Or Academia?

REWARD? Does this imply high reimbursement prices? Government subsidiaries? Or marketing exclusivity?

INNOVATION? Does this mean more patents? Small step improvements? Or transformative ideas?



My objective is to answer these questions before I run out of my allotted space.

To begin let's look at the track record of Japanese pharma in discovering new molecular entities (NMEs) and bringing them to the global market with actual or forecasted sales of more than US\$500 million or ¥50 billion per annum.

Year	Number of NMEs
1997	5
2005	22
In development	34

These numbers suggest the pace of innovation has increased since the early 1990's and shows no sign of abating. We can also conclude that Japan, along with the US and Europe, is a source of important, widely used new drugs. At the present time you cannot say the same for India or China. In fact, as we shall note later, what India and China are doing today transpired in Japan between 1950 and 1975.

To evaluate the rewards for seeking, finding, developing and marketing novel drugs and medical devices we need to follow the money. The fiscal year 2008 MHLW budget includes ¥27.4 billion to accelerate the development of innovative drugs and medical devices. It also includes ¥23.9 billion to prioritize and expand research. The METI budget includes ¥10.2 billion to accelerate commercialization of innovations.

This is a total of ¥61.5 billion to reward discovery, development, and commercialization of innovation. Compare this to a ¥240 million MHLW budget to promote generics. There is a lot more talk than money about promoting generics which by definition are not innovations.

Many other examples can be cited to support the argument that the Japanese government never has and likely never will promote old technology in any industry. This policy dates back to the late 19th century when Japan first opened its doors to the rest of the world. So the question is not Will Japan Promote Innovation? Rather, it is Will Japan Continue to Promote Innovation? At least through March 2009 the answer is a resounding yes.

We can also cite other rewards for the entire chain of discovery, developing, and commercializing innovations. I list them below in bullet point fashion:

- * New legislation which will allow firms to use the proceeds from government subsidized projects to improve R&D facilities and not repay the financial aid, in other words, the subsidy is a gift.
- * Strong IP protection and very few lawyers engaged in the practice of finding ways to invalidate patents.
- * Market exclusivity for six to eight years regardless of the patent status.
- * Higher reimbursement price premiums for various measures of innovation.
- * Rapid diffusion of new drugs because of few formulary restrictions.
- * Long "tails" for old drugs because of low generic competition.

Next, let's quickly review the history of Japan pharma from zero innovation to transformative innovation.

Post WWII to Early 1970's

- * No discovery research in Japan.
- * New drugs received through licensing in or via a joint venture with a foreign firm because Japan was closed to 100% foreign ownership of pharma companies.

1975 - 1990

- * Discovery research focused on small step innovations, i.e. 2nd and 3rd generation products.
- * Product patents replaced process patents.
- * Japan open to 100% foreign investment
- * Licensing out begins

Note: Pharma companies in India and China are going through this phase of development at the present time. One difference is Japan was never a big API producer nor did Japanese companies produce generics.

1990 - 2000

- * Discovery research focused on 1st generation products.
- * Market exclusivity extends product life cycles.
- * Foreign share of the market increases.

2000 - Present

- * In-house discovery research supplemented through acquisition of platform technology and early stage products.
- * Consolidation among large cap pharma companies to focus more research money on fewer therapeutic categories.
- * Significant moves to acquire businesses in the US. A critical mass presence in the US market is the highest priority for large cap Japanese pharma companies.

Now let's look at the future challenges and opportunities for innovation in Japan.

Challenges

Number of Bio-Technology Patents Published in Japan by Country of Origin

	1997	2005
Japan	671	2,138
US	721	1,683

As noted above, Japan lagged but then caught up with then exceeded the US by 2005. However, the number of patents is an imperfect proxy for innovation as a patent does not necessarily translate into an innovative drug.

Japan's emerging biotech sector is hampered by the immaturity of venture capitalists and the low amount of funding available to develop innovative "seeds". At

present the market cap of Japan's biotechs is US\$4 billion. The US is over US\$400 billion and Europe is US\$41 billion.

The drug lag delays companies from reaping an early return on their R&D investments. To compound the challenge, downward reimbursement price revisions every two years cause companies to operate in a deflationary environment.

These two factors are severe constraints on the growth of companies operating only in Japan.

A final warning sign is the recent closure of several foreign research facilities in Japan. Does this mean these smart people do not believe Japan is source of innovation?

Opportunities

* Specific actions are being taken to eliminate the drug lag. While Japan speeds up its review process the FDA is slowing down.

* Industry/academia collaboration is beginning to blossom albeit far behind the US. This will be

driven by a more flexible labor market and more young entrepreneurs not shackled by past practices.

In short

Japan has and will continue to be a source of transformational innovations. These will be grafted on to Japan's demonstrated ability to make incremental improvements.

Rewards for innovation will come from a variety of sources thus bolstering the output of innovative products that will transform Japan's big pharma into global players.

P. Reed Maurer enjoys meeting people who are coming to Japan versus those leaving Japan.

