



# INSIDE CHINA: From knockoffs to knockouts

In the third article of this China-focused column, Michael Alper of NeuvoMedica takes a look at how China is moving away from being a copycat manufacturer and is fast becoming a global medtech innovation hub

Over the past 20 years, China's medical device market has grown to be the 4th largest market in the world at around US\$20bn. During this time, local companies and local talent in this industry have developed quite significantly and local companies' sales now make up almost half of the market.

But up until recently, most local medical device companies developed their product portfolio by imitating and even blindly copying existing products from multinational companies. This was often done with limited knowledge of how the products work and the reasoning behind the design specifications.

This had a lot to do with the market situation in the past. A lack of talent, lax IP laws as well as limited local competition made this strategy feasible up until a few years ago. However, now with more competition, a stricter IP regime and a much broader talent base, local companies realize that they must find new sources of innovation in order to compete.

In addition to this trend, the Chinese government has made it a priority to help develop the domestic medical device industry by supporting innovation. In its 12th Five-Year Plan, the government set local innovation in the medical device industry as a key initiative with ambitious development goals set for 2015 including issuing 200 new patents and developing 50-80 key medical device products, among other things.

Supporting this plan, the China FDA in March this year issued a "request for comment" draft of a new regulation that is supposed to expedite the regulatory process for domestic innovative medical devices.

Typical of the Chinese government, they are putting money where its mouth is with a RMB1.5bn (~\$250m)

special supporting fund for the medical device industry whereby companies can receive over RMB10m (~\$1.7m) from the government. This is only the start as the government has also announced plans of a RMB10bn (~\$1.7bn) fund to support domestic innovations in the medical device sector by 2020.

Jumping on the bandwagon, many multinational companies have been setting up or accelerating their local innovation center investments, especially in the last two to three years. These include companies like J&J, Fresenius, GE, Medtronic, Boston and Covidien who all recently set up new R&D centers. Some of these R&D centers, like Covidien were set up not just to create innovative products for China but also for the rest of the world.

There are many benefits for foreign companies to set up local R&D centers and manufacturing, including access to talent, access to government subsidies, as well as enjoying the benefits of improved reimbursement and sometimes an easier regulatory path.

There are already many examples of innovation in China developed both by local companies and by the China R&D centers of multinational companies. For instance, Microport, though originally started by imitating multinational companies' bare metal stents, went on to develop its own IP for drug-eluting stents (DES) among other new product lines. It is now on its third-generation DES, with unique design innovations that give the Microport product a competitive edge. GE had developed in its research centers in China an innovative portable ultrasound designed specifically for use in the country's rural areas and which eventually found applications in the US and other developed markets.

Much of the medtech innovation in China today leverages the internal R&D resources of these companies, coupled with collaboration with physicians, research institutes and academic institutions. The China Strategic Alliance of Medical Device Innovation (CSAMDI) was one of the organizations formed to help bring academic institutions and companies together to forge such collaborations and many of the most well-known Chinese medical device companies and academic institutions are members.

Innovation is not something that only the largest Chinese companies are seeking. Smaller players in the medical device space like Grikin and Sanyou Medical have worked closely with top physicians to come up with new innovative products in the orthopedic and vascular area, respectively.

Not limiting themselves to the research institutes and academic institutions in China, there are some companies like Puyi Shengji Technology who are aggressively looking to establish partnerships with foreign institutions and companies to help drive their innovation here in China via technology transfer and other means.

For small and medium sized foreign companies that wish to leverage the benefits of local innovation and manufacturing, the option to partner with local companies can be quite attractive if an appropriate long-term win-win scenario can be negotiated. With new regulatory policy expected to come out in the next few months that will put the same local clinical trial requirements on imported products as for domestically made products, I see such an option becoming a possible future trend.

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