US health reform burden falls on medical devices

Like many other industries, makers of medical devices are reeling from the anticipated effects of US healthcare reform. But, unlike other businesses, which might only have a faint idea of what the coming changes mean, medical device companies have a concrete notion of the future effects on their revenue, namely a 2.3% excise tax that starts in 2013. That burden could spell trouble for research and development of medical devices in the US, according to experts.

The tax, which was signed into law in late March as part of the healthcare reform bill, is expected to raise $20 billion over the course of a decade. And because the 2.3% is an excise tax, purchasers of medical devices—including hospitals, doctors and researchers—can indeed expect at least some of that money to come out of their pockets as prices go up.

"It's likely going to end up split between companies, with what the excise tax means for price varying from product to product and company to company," says David Nexon, senior executive vice president for AdvaMed, the Advanced Medical Technology Association.

Of greater concern to medical device makers will be how the tax affects their bottom line. Although companies with less than $5 million in revenue each year will be exempt, small companies just above that threshold could be hurt the most. An analysis by MassDevice, the Massachusetts Medical Devices Journal, estimated that some small companies could have their profits cut by as much as half, whereas companies in the red could go even further downhill.

According to Mark Leahey, president of the Medical Device Manufacturers Association (MDMA), which represents about 250 small- and medium-sized companies, lost profits could mean one or a combination of four things: shutting down entirely, a reduction in overall staff, outsourcing to other countries, and cutting the research and development budget, which Leahey says will be the "lion's share" of changes.

Nexon agrees, noting how "cutting R&D hurts less than cutting staff." And as large companies will merely trim their budgets, it's likely that the smaller companies, many of them focused on innovation, will go under entirely. Leahey says that MDMA and other groups will work together to ensure that individual companies keep their footing. Talks are also ongoing in Washington, DC to pursue a new bill that would soften the tax burden for developing companies, for example by exempting their first $100 million in sales.

Those sales, however, might not go up significantly because of healthcare reform. Leahey notes that whereas other industries also being taxed are likely to benefit in the long term from new patients—pharmaceutical and insurance companies, for example—medical devices "are used whether or not someone has insurance." Massachusetts, after its own health care reform in 2006, had "no noticeable uptick" in sales, according to Leahey.

However individual companies pan out stateside, the US medical device industry as a whole will be wary of its global standing once 2013 rolls around.

"The US has been dominant in this industry for years, and we'd like to stay that way," Nexon says. "India, China and Brazil have all been making investments into the medical device industry, so the tax is likely going to be bad for our standing in the long term. How bad, however, is hard to quantify."

Christian Torres, New York

Ariad patent decision points to description dilemma

Much of the recent press attention relating to gene patents has focused on a US federal judge's decision to overturn Myriad Genetics' patent on two breast cancer genes, *BRCA1* and *BRCA2*. But around the same time another important ruling was issued.

After almost eight years in the courts, the biotech company Ariad ultimately lost its patent claims relating to cellular pathways that involve the transcription factor NF-kappa B.

The broad patent, granted in 2002 to several universities and licensed to Ariad, hypothesized that three classes of molecules had the capability to reduce NF-kappa B activity (*Nat. Med.* **8**, 1048, 2002). But it did not detail the substances that have such action. The final US Federal Court decision issued in late March reaffirms the requirement of a 'written description' showing that the inventor possessed the claimed invention at the time of filing.

Ariad, of Cambridge, Massachusetts, had taken Eli Lilly to court for infringement with two drugs that tuned down NF-kappa B activity: the osteoporosis treatment Evista and the sepsis drug Xigris. Ariad won in 2007, but Lilly successfully appealed the following year. This latest federal court decision marks the conclusion of Ariad's subsequent appeal.

Eli Lilly and Company

The winner: Eli Lilly headquarters in Indiana.

The court's decision makes patentees' timing crucial, says George Best, partner and intellectual property litigation expert at the law firm Foley and Lardner in Palo Alto, California. Too early and you might not meet the possession requirement, too late and competitors might get there first.

Although the decision is broadly welcomed, the use of the written description requirement is controversial.

"The problem with using written description is that the standard for compliance is entirely amorphous," says Chris Holman, associate professor of law at the University of Missouri–Kansas City School of Law. It also makes it more difficult and expensive for patent applicants to get adequate patent coverage, he says.

Ariad's sole remaining legal option is a petition to the US Supreme Court, although Holman and Best deem this highly unlikely.

Nevertheless, Harvey Berger, chairman of Ariad, said in a statement that the company is reviewing the ruling "to assess our options in the case."

Bea Perks, Cambridge, UK