AN AUDIENCE WITH…

Paul Herrling

Paul Herrling, Head of Corporate Research, Novartis. Paul Herrling is Head of Corporate Research at Novartis and Chairman of the Novartis Institute for Tropical Diseases (NITD) in Singapore, with a lead role in setting up the company's collaborations for research on neglected diseases. One example is a recent collaboration in Indonesia with the Hasanuddin University Clinical Research Institute in Makassar and the Eijkman Institute in Jakarta where Novartis will conduct epidemiology and diagnostics research into tuberculosis and Dengue fever. Herrling assumed his current position in 2002, having previously been Head of Global Research at Novartis Pharma and a key player in the formation of the company, which formed after the merger between Sandoz Pharma and Ciba–Geigy in 1996. He is also Professor of Drug Discovery Science at the University of Basel, Switzerland, and holds a Full Adjunct Professorship at the Scripps Research Institute. Here, he tells us about Novartis's recently unveiled plans to extend its research and development (R&D) operations to China.

Why has Novartis recently decided to have an R&D presence in China?

I've been convinced for many years that it would become important for Novartis to have not only commercial and manufacturing activity in China but also R&D. In our US laboratories, a large group of our scientists are Asian and we could see that they were beginning to move back to China because the scientific research environment was becoming more attractive. For 9 years I have been setting up the annual Corporate Research Symposia in China on special topics and these gave us a sense of how the research situation was evolving. Eventually, Novartis's Chairman and Chief Executive Officer, Daniel Vasella, and Mark Fishman, President of the Novartis Institutes for Biomedical Research, felt that the time was right to move into this region. So Mark and I went to look at the site where the institute is going be — at the Zhangjiang Hi-Tech Park in Pudong New Area, Shanghai — and we selected a piece of land that was within walking distance from one of the large research hospitals. Research here will focus on virus-dependent cancers, such as Epstein–Barr for nasopharyngeal cancer and hepatitis B for liver cancer, and because these diseases are prevalent in Asian individuals it was important for us to have direct access to these patients.

Would you expand on your comments about why Novartis opted to do this in China rather than India?

In terms of talent, India and China have equally brilliant people, but there are issues relating to data and intellectual property protection in India that are not amenable to innovative R&D. There is no data protection in India, which means that if you submit a dossier as part of an application for drug approval, it is immediately accessible to all competitor companies. But the biggest factor is the patent situation. When India brought in its Patent Act in 2005 it made its own amendments to the World Trade Organization's Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement. These amendments essentially provide no patent protection for companies developing innovative drug products, because they do not allow the patenting of incremental improvements, which is often the way that science advances. This is why there is currently a dispute over Gleevec (imatinib). The issue is not about Gleevec specifically, because Novartis supplies Gleevec for free to 99% of patients prescribed it in India, but is about the principle of adhering to the TRIPS agreement. A country's compliance to TRIPS can only be contested by another country and not by a company. So we needed a concrete example to take to court. When India rejected a patent for Gleevec based on these amendments Novartis was able to dispute the decision based on what it feels is an incorrect interpretation of TRIPS. Interestingly, the Indian government was itself so unsure whether this particular amendment was compliant with TRIPS that it appointed a committee (chaired by the Director General of India's Council of Scientific and Industrial Research, Raghunath Mashelkar) to investigate this further. The report supports our view that although precautions have to be taken against 'evergreening' (when companies patent several different uses or properties of the same drug), the amendment as it stands does not seem to be compatible with TRIPS.

> “India's ambiguous attitude towards patent protection [makes] the situation simply not attractive to us”

By contrast, China has taken on board all of its obligations under the TRIPS agreement and it is now just a matter of implementing these laws. Obviously it takes time to build up the number of patent lawyers and people in the courts who are then able to handle these cases, but they are really moving forward in this area. It's not perfect, there are still areas in China that are lagging well behind, but as a whole you can see that the law and intention of the Chinese government is moving in a direction that enables us to do our work there. In India, because of the amendments and, if I may say, India's ambiguous attitude towards patent protection, the situation is simply not attractive to us.

How do you see the situation being resolved?

Many feel that this stance is not in the interest of the innovation-based pharmaceutical industry, both globally and locally. Ranbaxy Pharmaceuticals pointed out that if it wants to conduct innovative research it will be hindered compared with companies from other countries. So there is currently a division in the pharmaceutical groups in India between those that want to be able to continue to copy drugs that are still under patent in the rest of the world, and those that want to do their own value-added, innovative research and would like to see India's patent laws more aligned with TRIPS. So, it needs to be addressed at two levels. The first is the legal question of whether the amendments India has made are consistent with the TRIPS contract that they signed, and for that we will have to wait for the court's decision. But then there is also India's internal politics and as outsiders we can only say what we would like to happen. Ultimately, India's government will have to decide which way it wants to go.

Interview by Joanna Owens