Leon Serry
FOUNDER AND FORMER MANAGING DIRECTOR CIRCADIAN TECHNOLOGIES LIMITED

# It's time to keep the profits home...

## With tax breaks for phase 3 human trials Australia could create a Swiss-style pharmaceutical industry, argues Leon Serry.

Swiss pharmaceutical companies Novartis and Roche – capitalised at $152 billion and $131 billion, respectively – are each bigger than the National Bank of Australia and BHP Billiton.

That two such enormous and successful companies have developed in a country with a population of only eight million says a lot about the ingenuity and far-sightedness of the Swiss. It also indicates the potential that exists in Australia with a population of 23 million and worldwide acknowledged scientists.

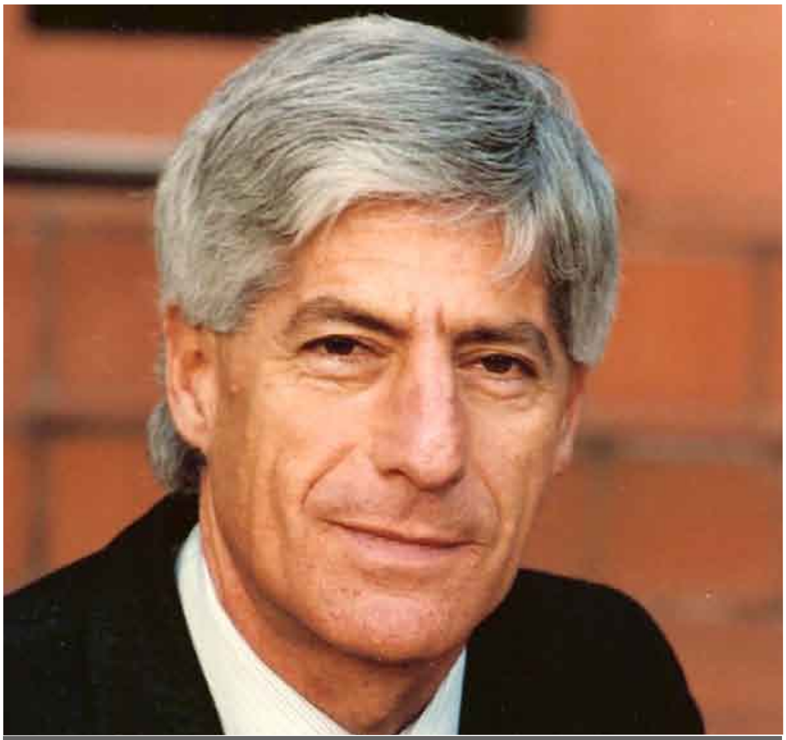
The Swiss developed a pharmaceutical industry second only to the USA in a country smaller than Australia, and with no distinct competitive advantage in the area.

Crucial to the survival and prospering of both Novartis and Roche is their ability to keep adding to their line of new products by in-licensing drugs from biotechnology companies and research institutes outside Switzerland that do not have the funds to take these drugs through to production and sale.

For Australian biotechnology companies it would be almost impossible to raise enough money to take their drug candidates through crucial phase 3 human trials, which are necessary before authorities give permission for a drug to be marketed.

This is despite the often ground-breaking ideas and access to excellent universities and research institutes such as the Walter & Eliza Hall Institute, the Baker Medical Research Institute and the Murdoch Childrens Research Institute.

The cost of such trials could be in the region of $120/$200 million. Few Australian institutional and retail investors are willing to invest this sort of money in phase 3 trials, even though drugs that reach this stage of development have around a 70% chance of reaching commercialisation, with the potential for significant returns.



*Leon Serry founded Australia's first listed biotech company, Circadian Technologies Limited, and was its Managing Director for 23 years.*

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The unfortunate consequence is that the likes of Novartis and Roche – and giant US pharmaceutical companies like Pfizer and Eli Lilly – could in the future make millions of dollars, and employ many thousands of people as a result of Australian ideas and research.

In all likelihood, Australian biotechnology companies will end up providing worldwide exclusive licenses for their drugs to large international pharmaceutical companies in exchange for milestone payments and royalty streams of approximately 7%. Such a licensing scenario will not create jobs in Australia, will not develop a manufacturing industry, and will not yield export income. The international pharmaceutical companies will take the drugs through the final stages (phase 3 human clinical trials) to commercialisation and reap the greater benefits.

The Australian Government has supported biotechnology, particularly the early development of biotechnology companies, via various initiatives including Start, BIF and ARC Linkage grants, NHMRC funding, R&D Tax Credits and the more recent Commercialisation Australia grants and loans program. Further such assistance programs are still needed at the early stage.

However, thereafter is little help, with potentially huge rewards of early-stage Government support being lost if a project is licensed to an international pharmaceutical company for its final stages of development. A successful pharmaceutical drug can easily achieve annual sales in excess of $1.5 billion per annum, and some major drugs achieve sales in excess of $4 billion per annum.

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While investors have shown support for phase 2 human clinical trials in the past, there is a need for the late stage phase 3 human trials to be funded locally via substantial capital raisings on the stock market.

The industry would be greatly enhanced if there was provision for a tax deduction to investors who invest in drugs that are entering phase 3 human trials. In addition to enabling a biotech company to raise funds for the phase 3 trials, it also provides incentives for investors to back early biotech start-ups knowing that if a drug was successful, there is a reasonable chance of securing funding for a phase 3 study.

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If a compound is invented/discovered in Australia and successfully completes a phase 2 trial, then the company developing the compound should be eligible to obtain tax concession funding for its investors as follows:

1. Subscriptions for the cost of a phase 3 human trial should be eligible for a 100% tax deduction provided the investment is held by the investor for at least one year.
2. The compound has to be developed or discovered in Australia.
3. The tax deduction would not be available for nutraceuticals and vitamins.
4. The deduction would be available to both retail and institutional investors.

An additional point could be that in the event a biotechnology company receives a takeover bid, it would have to repay the tax benefit received by its shareholders (at a 30% rate) together with interest to the taxation department.

Eligibility for the tax deduction to investors could be capped at say $500 million per annum in total to be spread over the eligible companies, thus limiting the cost to Government.

In addition, further significant funding would be secured if financial institutions and superannuation funds were required under legislation to allocate 0.1% of their investable funds for the late-stage human trials of biotechnology companies. They would also receive the tax benefit for the late-stage trial funding.

At most, maybe two Australian biotechnology companies would undertake phase 3 trials in any one year.

In 2004, I presented this initiative to the then Treasurer, The Hon Peter Costello, the Minister of Science and Deputy Leader of the House, The Hon Peter McGauran, and the Premier of Victoria, Mr John Brumby at separate meetings with each of them. They all applauded the initiative and concept. However, to date the Government has not seized on this opportunity.

This is despite Australian Governments having supported the development of other local industries in this way in the past. Subscribers of capital to mining companies in the early 1980s received a 100% tax deduction which helped create companies such as Western Mining Limited. This was quite costly to the Government as tax concessions were given to very early start-up mining companies rather than to mining companies that had already discovered a deposit and required the funding for mine development.

The mining industry and the likes of Western Mining Limited (now part of BHP) were recipients of a tax deduction for early funds provided by investors for their risky mining projects and Australians are now receiving the benefit. The mining boom will not last forever and may have already peaked.

Now is the time to think outside the square and invest in Australia's scientific resource. Australian scientists publish 50% more of the world's scientific research per capita than the OECD average. My tax break initiative detailed above will provide a very strong endorsement for the future of the Australian pharmaceutical industry. The biotech industry needs support. Only one biotech company has listed to the ASX in the last three years as compared with 30 mining companies in 2009 with mining listings happening every week since.

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The former U.S. president, Bill Clinton, declared January 2000 a National Biotechnology month. He said at that time "as we stand at the dawn of a new century, we recognise the enormous potential that biotechnology holds for improving the quality of life here in the United States and around the world."

We need Bill Clinton's emphasis on science and discovery in Australia. We are the clever country, however we must adopt the former President's dynamic vision for science and healthcare, firstly to improve the quality of life for all and secondly to create wealth for Australia that comes from being innovators and developers of pharmaceutical cures and products.

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