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IP and Health

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We would all agree that keeping patients out of hospital and out of long term care facilities or at least reducing their length of stay in either of those institutions – is a worthwhile objective.

As well as the important intrinsic value to the patient and their family, it is simply cheaper to society as a whole.

Now, we can achieve this goal to some degree through appropriate use of preventative health strategies, most people's first choice, and we can also maximise the gains to patients through another strategy – more use of drugs!

By which I mean greater use of new and more effective pharmaceuticals including the emerging biotech drugs. Given that I am a consultant to Medicines Australia, the primary representative of the major pharmaceutical companies in Australia, you might say "well he would say that" and of course, self interest is always a good motivator.

However, in this case logic and sound economics as well as the best interests of the patient are also on the same side and that makes the case compelling.

Extensive research by Dr Frank Lichtenberg of the Columbia University Business School has demonstrated that new pharmaceuticals introduced between 1986 and 2000 – just 14 years - have added 9.5 months to the life of every person in the room and indeed, every Australian. Potentially more to the life of the average resident of the United States because of their greater access to new, innovative, medicines.

These same drugs have also kept older people in their homes longer and delayed their entry to long term care. They have delayed heart attacks and strokes as well as broken bones and debilitating conditions like osteoporosis. Simply keeping people at home longer is a worthwhile social objective for the families concerned as well as a financial benefit to Treasury.

New and innovative medicines are not invented without massive investment and considerable risk. It is a perilous journey for the new candidate molecule and the company that sponsors it on the journey from the lab to the corner pharmacy.

There is no exact dollar value for the amount required but estimates put the figure at around AUS\$1.3 billion to bring a drug to market these days and it might take from 10 to 15 years with the longer period usually reserved for products like vaccines.

Pharmaceutical companies in the United States spent more than US\$50 billion dollars in research and development related activities in search of new medicines in 2005 alone.

No one can undertake this kind of commitment without the prospect of a return at the end. Especially when most of the prospective molecules drop out of drug school along the way. Many enrol but few graduate. Standards are rigorous, as they should be, and failure can come late when accumulated costs are high.

Society as a whole benefits from the work of those who invent these medicines and take the financial risks associated with their development and they represent the classic case for the awarding of a state monopoly for a fixed period to allow the inventor time to recover monopoly profits in exchange for that risk, effort and innovation.

This procedure has a long history.

The issue of “letters patent” by the English Crown granting a monopoly to a particular supplier of goods or services dates back as far as 1449 (to a Flemish glass maker to provide stained glass for Eton College). However, it would appear that the power to grant monopolies was apparently too corrupting for the Sovereign and Parliament regulated the situation with the Statute of Monopolies in 1623.

While the Statute generally condemned monopolies, it did grant the first inventor of a given item 14 years of exclusive rights to their invention subject to certain qualifications:
...“*they be not contrary to the law nor mischievous to the state by raising prices of commodities at home, or hurt of trade, or generally inconvenient.*”

This was the first statutory patent and not a great deal has changed since. Indeed, back in 1787, the Framers of the United States Constitution captured the spirit and purpose of the patent system perfectly in the phrase they used to authorise the Congress to provide for them:

To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries;

Those who drafted the Australian Constitution over a century later used a more prosaic phrase when they simply authorised the Commonwealth Parliament to make laws with respect to:

Copyrights, patents of inventions and designs, and trade marks:

To some extent that transition over time has continued to date and that is my fear. We need to regenerate the widespread respect for and understanding of the basis for which patents are granted.

Increasingly, especially in the case of expensive life saving medicines developed by profitable multinational companies, some in society mistakenly see the intellectual property rights or patent protection offered by the law as a monopoly right to exploit a profit from the weak in society and from the poor of the world.

There is insufficient time this morning to look in detail at the range of issues in this complex topic so it is worth returning to the work of Dr Lichtenberg because he is one of the few who has undertaken the detailed statistical research necessary to uncover the strong links between innovative pharmaceuticals and health and therefore between IP and health.

In his 2003 paper¹ for the US National Bureau of Economic Research to which I alluded earlier, Dr Lichtenberg demonstrated the clear link between the introduction of new molecules to a country and the extra years of life that the citizens of that country gain from the use of that molecule for medicinal purposes.

This is possible because of the extensive records of mortality and morbidity maintained by the World Health Organisation.

¹ Dr Frank Lichtenberg, *The Impact of New Drug Launches on Longevity: Evidence from Longitudinal Disease-level Data from 52 Countries, 1982-2001*. National Bureau of Economic Research 2003.

In general, life expectancy throughout the world at birth has grown from 47 years in 1950 to 65 years by the end of the last century. Most remarkably, it has grown even more rapidly in the less developed countries, with the gap between rich and poor countries halving in that period.

These are significant changes and the even more dramatic shift in the developing world is all the more noteworthy and begs for a more detailed explanation.

Fortunately, the meticulous records of the WHO faithfully document the inexorable rise in longevity of all citizens of the world (on average) and given the equally well documented (by IMS Health – a company that tracks new drug launches) it is possible to match drugs, mortality and morbidity with some accuracy.

When Dr Lichtenberg did this for his 2003 paper, he found that much of the increase in longevity throughout the world since 1982 can be attributed to new medicines. His final conclusion was that new medicines add about 3 weeks a year, each and every year, to the life of every person now alive in the United States. All those 3 weeks add up....

These drugs come at a financial cost and the new bio tech drugs come at a very high cost. Bio tech drugs are highly targeted, have a smaller patient audience and higher development costs and therefore higher selling price. Are they worth the cost?

To the individual who is sick, the answer is always yes, but to Governments with expanding health Budgets, words like “unsustainable” are used in Treasuries throughout the Western world.

At \$252, the annual per capita spend on pharmaceuticals² in Australia is not that high and the OECD average is just \$363 – not much for extra life span we have been discussing this morning.

All of this work is predicated on a sound IP law foundation. Without it, no one could invest the funds required to develop and test the new molecules required to maintain the impressive gains we have made so far.

The English Parliament, nearly 400 years ago, clearly understood that monopolies stifle innovation and competition but that a limited term monopoly in the form of a Patent was essential to promote and reward scientific creativity and invention.

The legislative successors of these laws exist today although more attention needs to be given to debates on IP law in the Parliament by Members and the media if we are to maximise the economic and health opportunities of one of the great enabling technologies the 21st century – molecular biology.

There is also a view abroad among some members in society that patents may stifle some forms of research and indeed that they may be fundamentally unfair to many underprivileged groups as well as less developed countries. Some of these countries have now resorted to the compulsory licensing of drugs for the treatment of AIDS thereby depriving the patent holder of the appropriate payments and control of the drug.

² OECD, “*OECD Economic Surveys – Australia*”, OECD Publishing, Volume 2006/12 – July 2006, p63.

Australia passed laws as a result of concerns about the US – Australia Free Trade Agreement which had the effect of reducing the rights of pharmaceutical patent holders and so the trend is not isolated to less developed countries.

The apparent ongoing success of our patent laws and the constant supply of effective new medicines has caused us to lose sight of the source of that success and the fragile nature of the intellectual and legal bargain we strike with those who provide the long term risk capital in this global enterprise of innovation.

A final example from the Lichtenberg study will demonstrate just how closely we depend on the flow of IP for our health.

In a related study, he examined prescription data from 12 million patients in a region of the US enabling him to link the “vintage” of the drugs they were using with the ultimate outcome of the medical intervention.

In this context, drug vintage means the year in which the relevant authorities approved the drug for use in the community.

It turns out that people who were taking drugs approved before 1970 had a 3 year mortality rate of 4.4% whereas those taking drugs approved during the 1990's had a 3 year mortality rate of just 2.5% even though otherwise all the patients were exposed to just the same advanced US health care system.

A difference like this is very significant and highlights the value of gains in the pharmaceutical industry of even incremental change.

Australia is famous for a Minister of Labour who once told Parliament in the early 1970's that he wanted every worker to earn more than the average wage.

And of course, it would be great if we could all live longer than the average age at death! Even Big Pharma can't achieve that statistical miracle but innovation will continue apace provided the fundamental building block of a strong IP law are in place and we have a society which values and understands the need for that law.

That is the cornerstone which underpins the investment in the next generation of medicines. IP is the intangible and invisible mechanism which prevents the otherwise inevitable market failure which would result in this vital area.

No one can risk the massive investment required in a product they could not protect or in the subsequent generations of those products which become more expensive with each generation, if they could not protect that investment with IP law.

Only those countries with strong IP law have significant discovery programs and it will always be so.

Our future health depends on the strength of our intellectual property laws almost as surely as it does on the skills of our scientists.

IP and Health

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Key objectives of “health”

- Keep people healthy.
- Reduce health costs to family and society.
- Increase productivity of otherwise sick people.
- Allow older people to stay independent longer.

Use more drugs!

- New drugs introduced between 1986 and 2000 increased life expectancy by over 9 months.
- Reduced incidence of stroke, osteoporosis etc allowing older people greater independence and reducing social costs.
- Allow younger people to return to work and pay taxes, the “Gleevec” effect.

But there is a cost!

- Drugs cost AUS\$1.3 billion and up to 15 years to bring to market.
- US Pharma companies spent US\$50 billion in 2005 on R&D.
- Many molecules are called but few are chosen.

Patents - the foundation stone

- 400 years of legislative history.
- *“To promote the progress of science....”*
- Are patents on medicines the goose that lays golden eggs or a capitalist trick to exploit the poor and sick? Something between?
- Need to reinvigorate public and Parliamentary understanding of the value of IP law.

Link between Health and IP

- Average global life expectancy up from 47 years in 1950 to 65 years by 2000.
- Lichtenberg shows clear link between new drugs and extended life span.
- New medicines add 3 weeks every year, compound.
- *Per Capita* spend on pharmaceuticals in Australia just \$252.

IP is key

- Without patent protection, no one could invest the funds required for drug discovery.
- Molecular biology - major enabling technology of the 21st century - depends on IP.
- Yet countries by-pass patents – HIV drugs.
- Australia and “Latham” amendments.
- That our IP laws still work does not mean we can be complacent about the future.

Incremental gain

- Lichtenberg shows even incremental gain is really valuable.
- Older drugs are much less effective.
 - Pre 1970's drugs = mortality rate of 4.4%
 - Post 1990 drugs = mortality rate of just 2.5%.
- This is true even in the context of one of the most advanced health care systems in the world.

Conclusions

- Without strong IP and patent law, no one can afford the investment in new medicines.
- One generation of drugs pays for the research and development costs of the next.
- IP is the mechanism that prevents otherwise inevitable market failure in drug R&D.
- Our future health depends on innovative science and strong IP laws, vigorously supported and well understood.