Editorial

Patent Medicine and Orthomolecular Medicine

"All drug doctors are quacks." (attributed to Benjamin Franklin)

My (AWS) father spent most of his professional life with patents. He began as a patent draftsman, producing many technical illustrations for Eastman Kodak Co. in Rochester, NY. And, although patent illustrators are not allowed to sign their work, he did so anyway. He used Morse Code, and concealed his name in each drawing's broken shading lines. Later, he became a paralegal in the company's patent department. It was at this time that he took me, as a teenager, with him to work one day. Actually getting to his office was strikingly reminiscent of the opening of the television spy spoof Get Smart. We went through door after locked door, most with uniformed guards. Once he went to Washington, DC, with an attaché case handcuffed to his wrist. Cool!

Not everyone knows that there is a patent and copyright clause in the US constitution. Article 1, famous for its protection of free speech, also states that patents are intended "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".1 A patent grants an exclusive right to stop others from selling, making or even using the invention for a long period, typically 20 years. The patent is a negative right that prevents others from profiting from the invention. Infringing a patent monopoly has legal implications, and typically the patent holder will demand to be compensated financially. In some countries, patent infringement is a criminal activity.

Patents are supposed to drive innovation. The profits that can arise from a patent are said to promote investment in R&D, design and technical improvement. Since the patent is a published document,

others can keep up with the advance of the technology. Licensing the technology allows inventors to get their innovations manufactured and marketed. However, a company may acquire a patent simply to prevent it being exploited by its competitors. This may actually prevent innovation. In medicine and health care, patents all too often fail to promote the progress of science, and may actually hinder it.

Technology or Science

Patents are for technology and engineering; they are not part of the scientific method. Science distributes its knowledge openly without direct financial exploitation. The double helix model of DNA of Franklin, Crick and Watson was published in a short paper, although Franklin was not included as an author. This was a scientific breakthrough and not subject to patent. Eventually, the DNA model would help drive whole new areas of biotechnology, packed with patents and monopolies. The underlying science however is free and openly available with no restriction on its exploitation. Similarly, Alan Turing's description of a universal computer was unpatented basic science. Later, digital computers and software would become a highly profitable technology driving innovation in the latter half of the 20th century.

The idea that people need to be given monopolies for new ideas is contradicted in that the typical patent is a minor technical advance. These patented, small technical advances directly depend on the increase in fundamental scientific knowledge.

Pharmaceuticals

Medical patents exploit the sick for profit. They provide exclusivity rights to drugs and treatments and prevent competition.² The problem has been highlighted by developing countries which are often unable to afford the inflated drug prices.³ Since these countries are not able to provide massive profits, the drugs that they need for malaria and other diseases may not be properly investigated or developed.

Recently drug companies have contributed a token portion of their profits to healthcare in developing countries. However, this can be interpreted as a minor aspect of public relations by companies that are characterised by marketing rather than R&D. Claims that patents and intellectual property laws contribute to a framework that allows for humanitarian and fair distribution of drug R&D are meaningless unless they are substantial.

The claim that drug companies need exclusive rights, a monopoly in the market, and inflated prices to reward the need for R&D is overstated and overplayed.⁴ The funds described as research and development may be exaggerated and can be lower than the marketing costs.⁵

Recent Nobel Prize winner Sir John Sulston described proprietary restriction on medicines as morally corrupt.⁶ The inequality in the availability of drugs has generated increasing anti-patent opinion. The lack of available HIV and AIDS drugs in several parts of the world has been a popular concern. Developing countries are challenging international patent law in medicine. Their argument is simple and could not be more clear: human lives are more important than profits for drug companies. Modern drug treatment for HIV/AIDS, tuberculosis and cancer are largely unavailable in many parts of the world. In 2002, Thailand switched to using generic antivirals manufactured in India, and the price dropped from over \$500 to about \$30. More recently, Brazil declared that the availability of the antiviral medication efavirenz was in the public interest and demanded appropriate prices. As the problems continue, other

developing countries may introduce local generic drugs, rejecting patents in favour of the public interest. Developing countries can override patent law in times of need but attempts to do so are likely to produce legal and political challenges.

Owning Life Itself

While the double helix was considered a scientific discovery belonging to humankind, it is now possible to patent genes. Patenting the genetic code is controversial and subject to challenge. A bill with the US Congress may invalidate patenting of human gene sequences.7 Patents on cells⁸ and whole living creatures9 have been applied for and granted. The scene was set for an entire higher animal to be patented, and sure enough, a patent on a mouse was granted to Harvard University in 1988.10 This Harvard mouse and its offspring are owned by DuPont with the registered trademark Oncomouse[™]. Perhaps the next step will be patented cheese to feed it. The patent for this particular genetic modification is extended to nonhuman mammals such as elephants or cats. However, objections to the patent in Europe, because plant and animal varieties were not patentable, were dismissed since the patent was not for a specific "animal variety".11 Similarly, humans are currently excluded-for now. Perhaps in future years the precise legal wording might not be taken to exclude humans containing a specific gene modification. By 2005, 20% of human genes were already subject to patent. 12 How far this takes us to the possibility of a new form of social Darwinism, or worse, where people are patented, trademarked, and owned, is an open question.

Medicine

Patents may be unsuitable for use in medicine and health care. Medicine is properly the application of science to health. This application involves technology and the potential for patents. However, there is an ethical dilemma. Should a monopoly be allowed on a life saving treatment? When should it be justified for a sick person to suffer and die, because the monopoly holder will not make a sufficiently large profit from the treatment?

Sick patients are vulnerable and their vulnerability increases with the severity of the disease. A terminal patient may be willing to sell their car, house, and the future of their family for a cure. Medicine has fought hard to acquire legislation to prevent the unscrupulous peddling of quack cures. Indeed, the very term "patent medicines" emerged in the 19th century as a phrase associated with charlatans and the exploitation of the sick. Today, the vast profits that can be made from monopolies and exorbitant drug pricing in medicine has led to an inversion. Patent medicines are now seen as the evidencebased answer to disease. They are not. Not one cell in the human body is made from a drug, patented or not. Nutrients, quite unpatentable unless modified, are not even close to being as profitable as drugs are. The fact that nutrients are often more clinically effective, and that nutrients are invariably safer, does not enter the patentpensive world of pharmaceutical finance. Nutrients are generic, and that's a dead end. Ascorbic acid at \$35 a kilo does not excite stockholders and does not excite accountants. Wonder drugs do.

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Are Antipsychotic Drugs Safe?

Antipsychotic drugs can kill. Orthomolecular physicians have known for many decades that the use of antipsychotic drugs for patients with schizophrenia and bipolar disorder only rarely helps the patient, and indeed can actually prolong the patient's illness. While in the short term they can help to bring some control to the condition, over the long term they interfere with the natural history of the illness converting what might have been a self-limiting state into one which is chronic and unrelenting.

For example, Bleuler, in his studies of the natural history of schizophrenia, long before the advent of the earliest antipsychotic drugs in the 1950s, showed