

BOOKS & ARTS

Testing times for genomics

In a bid to popularize the science and ethics of human genetics, two new books fail to address developments in gene testing since completion of the Human Genome Project, says **Kathy Hudson**.

Two new books attempt to bring the issues raised by the Human Genome Project before a broader audience. In *DNA: Promise and Peril*, geneticists Linda and Edward McCabe try to be tour guides. In *Just Genes*, bioethics consultant Carol Isaacson Barash tries to teach. Ultimately, neither book goes far enough to improve the public's understanding, and neither addresses contemporary problems that bedevil policy-makers and the public.

Barash provides an interesting, if poorly edited, historical account of ethically troubling genetic policies and programmes. "The goal of the book is to improve your ability to identify and analyze ethical issues," she says, and opens well with a description of the ethical principles and theories that could be applied to the issues raised by genetics. But that is the last you hear of them. Subsequent chapters discuss the familiar subjects of genetic privacy, genetics and human behaviour, cloning and the like, yet fail to demonstrate how the theories apply. Instead, Barash provides long lists of questions, often more than a dozen, for each issue. Knowing what questions to ask is an essential first step, but a teacher should help the reader critically evaluate these issues.

In *Promise and Peril*, the McCabes fare only marginally better as tour guides. They wrote the book in part, they relate, so that "your concept of your own identity can truly be liberated". *Viva la liberación!* But reading *Promise and Peril* is like visiting Paris with a guidebook written in the 1930s: the landmarks are mostly the same, but the political and social landscape is utterly changed. It is possible to find the Eiffel Tower, but where are the Internet cafes, the supermarkets and the ethnic restaurants?

Rather than chart unfamiliar territory for their readers, the McCabes, and to a lesser extent Barash, rehash the arguments about genetic determinism made more eloquently by Dorothy Nelkin and M. Susan Lindee in *The DNA Mystique* (W. H. Freeman, 1995). The McCabes declare that there is a widespread "perception that individual human futures are



New genetic tests raise questions about privacy, but their reliability poses a bigger problem.

fully described in the sequences within each individual's genome" and set out to refute it. Barash similarly asserts that genes are commonly viewed as "encapsulating our innermost essence". Most readers would agree that

a society that believes that traits, both medical and behavioural, are genetically hard-wired will ignore social policies and focus on genetic fixes. But how extensive is genetic determinism as a world view?

The McCabes argue that the notion that genes are not destiny has been "extremely difficult for some geneticists to accept".

This statement is puzzling. The tools of molecular biology and genetics, such as temperature-sensitive mutations, are rooted in the understanding that genes plus the environment equals phenotype. Disproportionate attention to genes arises not because scientists think that genes are everything, but because the genome is finite, knowable, and we have the tools to explore it. The complexity of the genome pales in comparison with that of human behaviour.

The favourite whipping boy in each book's

crusade against genetic determinism is the media. Yet serious studies of media representations of genomics fail to bear out their view, finding instead that determinism is seldom used by either the press or the public as a framing device for a discourse about genetics.

Both books devote considerable ink to privacy and genetic discrimination, especially misuse of genetic information by US health insurers and employers. Happily, the Genetic Information Nondiscrimination Act passed this year in the United States renders this discussion moot — the act will largely protect the privacy and integrity of genetic test results. Thus, the arguments forwarded by the authors can best be viewed as a historical footnote.

The most pressing policy question may not be the privacy of genetic test results, but the safety and accuracy of the tests themselves. This issue is at the heart of genomic medicine, yet is not addressed in either book. Barash mistakenly concludes that "deciding when pharmacogenetic testing is appropriate for commercial use will involve demonstrable proof of clinical validity and utility". In reality, genetic tests — including pharmacogenetic tests — can enter the marketplace and be sold directly to consumers without

Just Genes: The Ethics of Genetic Technologies

by Carol Isaacson Barash
Greenwood: 2007. 288 pp.
\$49.95, £27.95

DNA: Promise and Peril

by Linda L. McCabe and Edward R.B. McCabe
University of California Press:
2008. 356 pp. \$39.95, £23.95

any assessment of their usefulness or validity in a clinical setting.

The omission is notable given that Ed McCabe chaired the US Department of Health and Human Services Advisory Committee on Genetic Testing during its evaluation of genetic testing oversight. This committee concluded that government regulation was inadequate and put forth a series of policy recommendations. Because none of these recommendations was adopted, the issue still looms large — both for genetics and

geneticists, and for medicine more broadly.

Good guidebooks should point out new attractions as well as old, and new texts permit to cover contemporary issues as well as the historical. Neither the McCabes nor Barash accomplish this — both books are rooted in past discourses and ignore current issues of greater public health and policy urgency. ■

Kathy Hudson is director of the Genetics and Public Policy Center, Johns Hopkins University, 1717 Massachusetts Avenue NW, Washington DC 20036, USA.

contrast, organic chemistry is more than a century old, so the boundaries of patent claims are written clearly enough for competitors to understand what is claimed and what is not. Thus, companies can avoid infringement or resolve disputes quickly. Finally, the authors blame judges for expansionist tendencies that lead them to allow patents on “everything under the sun made by man”, resulting in a flood of biotechnology and software patents.

Bessen and Meurer use a lively, assertive style and are critical of patent-system stakeholders, including federal judges, the USPTO and patent lawyers. Throughout the book, they contrast the patent system's rules about claim boundaries with the supposed success of real-estate law, a system that has clear, surveyed and publicly available land boundaries.

In the late 1990s, the authors contend, the US patent system failed publicly traded corporations. They estimate that the cost to such businesses of litigation over chemical and pharmaceutical patents was around \$4 billion in 2000, but this was more than outweighed by the profits associated with patents of about \$15 billion, a questionably low number given the value of blockbuster drugs. But for other industries, litigation costs were about \$12 billion and the profit was only about \$3 billion, also a questionably low number, and a net social loss. The authors recognize that owning patents always provides a competitive advantage for individual companies, even if the overall industry would be better off without them.

The authors offer several suggestions. Force inventors to clarify ambiguous claims with the USPTO. Convince judges to invalidate claims that are not definite and clear. Empower the

USPTO to give pre-litigation opinions on claim scope and infringement. Increase renewal fees to prune out unused patents. Establish a prior user defence so that independent discovery and use of a patented invention is not considered infringement.

Admirably, Bessen and Meurer reject what they call “faith-based policy” based on unsubstantiated beliefs about how patents help or hurt different companies and industries. Instead, they aim to provide the “first comprehensive empirical evaluation of the patent system's performance”. They do well with studies of famous patent disputes, such as Kodak versus Polaroid (regarding instant

The cost of vague patents

Patent Failure: How Judges, Bureaucrats, and Lawyers Put Innovators at Risk

by James Bessen and Michael J. Meurer
Princeton University Press: 2008. 352 pp.
\$29.95, £17.95

Adding fuel to the anti-patent fire, James Bessen and Michael Meurer argue in *Patent Failure* that US patents cost more than they should because their claims are too vague. Patent claims define the scope of a patented invention, and when they are unclear, competitors cannot determine whether or not they are infringing the patent and whether they should license or litigate.

Bessen and Meurer argue that ‘fuzzy’ claims for abstract inventions such as software, biotechnology and business methods make patents too expensive to society. Chemical and pharmaceutical patents, however, produce net economic benefits, as do patents obtained by small companies.

The authors spend most of their energy attacking software patents, describing skyrocketing litigation costs, increasing uncertainty, the thousands of patents on a single product, and other problems that hinder software innovation. They ask why the system works more poorly for software and biotechnology companies than for pharmaceuticals and chemicals. Their research leads the authors to posit several explanations. First, claims on small molecules are clearer and more comprehensible than the abstract claims in

biotechnology and software patents.

Second, the US Patent and Trademark Office (USPTO) and courts unwisely permit ‘premature’ patent claims on biotechnology and software products that have not and cannot yet be made. For example, Amgen's patent on a method of making the red-blood-cell protein erythropoietin in hamster cells claimed all “non-naturally occurring” erythropoietin, including that made in human cells, even though erythropoietin had not yet been made that way.

Third, the courts have allowed patenting of early-stage biotechnology and software inventions that remain inchoate and abstract, increasing the likelihood of litigation against someone who independently develops an invention that falls within the scope of a patent claim. Fourth, patent law is in flux for the new fields of biotechnology and software. By



Microsoft's legal chief Brad Smith (bottom left) and lawyers wait for a 2007 decision at the European Union court that fined the company over expensive patent licences.