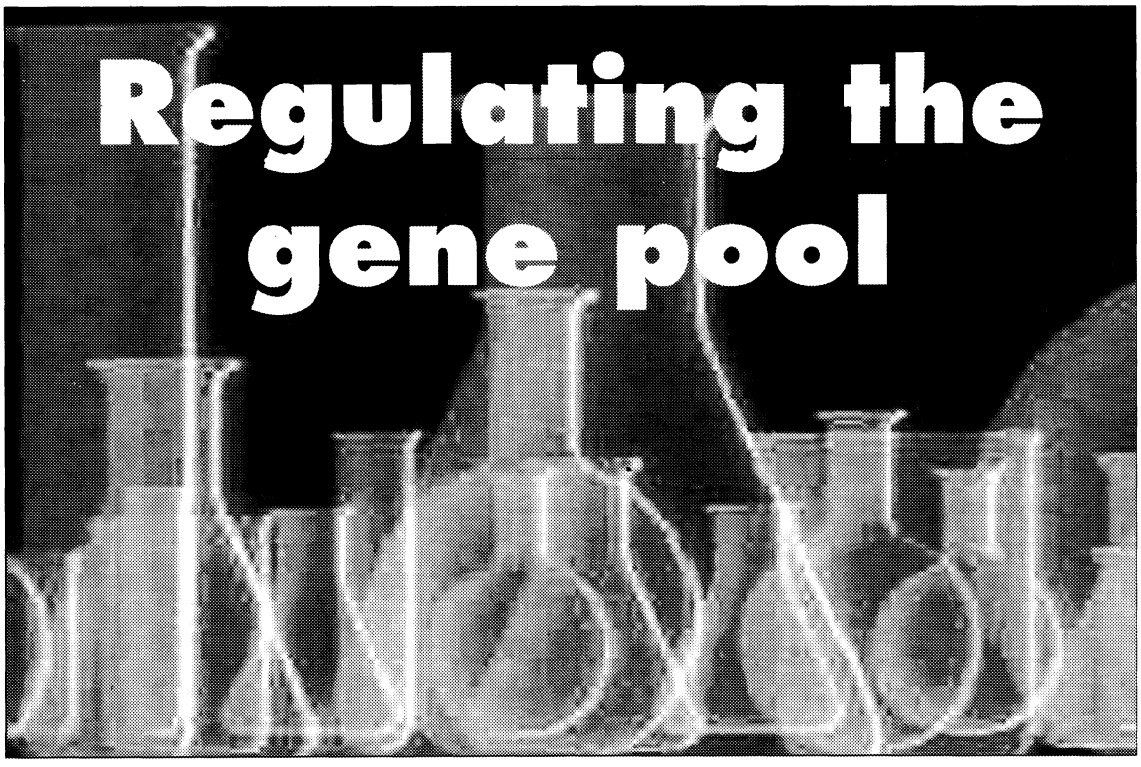
Regulating the gene pool



by Francis Wilkins

The last decade's explosion in global communications changed dramatically the nature of intellectual property law.

Almost overnight, lawyers had to rethink concepts such as "publication" and "circulation area". New concepts, such as an author's "electronic rights", were brought in to meet new needs.

But just as a legal model has begun to emerge that accommodates the internet and the web, so another IP revolution is well underway.

This time, the driving force is biotechnology, epitomised by the cloning in 1997 of Dolly the sheep.

And this time, the concepts that need to be re-thought go right to the heart of what it means to be human.

As the biotechnology industry develops, lawyers – indeed, everyone – will have to reconsider, quite literally, the meaning of "life".

Cloning and genetic modification are two of the more high-profile aspects of biotechnology.

Broadly, the term refers to the application of biological discoveries in the development of industrial processes and the manufacture of products ranging from foods and medicines to renewable energy sources.

It is, however, the more controversial aspects of biotechnology that raise some of the most challenging legal questions.

Regulating gene technology

The Commonwealth *Gene Technology Act 2000* – part of the effort to ensure regulation does not fall too far behind science in this rapidly developing area – has established a comprehensive program for the regulation of gene technology in Australia.

This Act, which commenced on 21 June 2001, takes a risk management-based approach.

All "dealings" with genetically modified organisms (GMOs) are prohibited unless approved under one of four risk-based categories, one of which includes a licensing requirement.

Processes regulated by the legislation include the breeding, growing, propagating and manufacture of a GMO.

Experimenting with a GMO and using the organism in the manufacture of a product that is not a GMO are also regulated, as is the possession, use, transportation – including importation – and disposal of a GMO.

The act bans the cloning of human beings, but does not otherwise regulate

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regulating the gene pool (cont)

somatic cell nuclear transfer technology (cloning) experiments, provided they do not involve the transfer of genetically modified material.

The Act does not, however, regulate somatic cell genes therapy for human beings.

GMOs covered by the Act include organisms that are able to reproduce or transfer genetic material and which have had their genes or genetic material modified in any way, as well as any organism that the regulation declares to be a GMO.

To be approved, dealings must fit into one of the following categories:

- "exempt", dealings that occur in a contained environment (such as a laboratory) and involve no intentional release into the wider environment;
- "low risk dealings", which can be undertaken subject to specified risk management conditions; and
- "registered dealings", likely to be licensed and considered very safe.

All other dealings need to be licensed by the Office of the Gene Technology Regulator.

The license required will depend upon whether an intentional release into the environment is involved.

"The biggest benefit (of the Act) is that we now have a national system that regulates gene technology and which is open," Lisa Di Marco, senior associated with Blake Dawson Waldron's Sydney office, said.

"The broader public is now able to find out what is going on in gene technology research."

The Act includes a two-tier consultation system for licence applications.

When a party applies for an intentional release license, the Act requires a much broader level of consultation than for non-intentional release licenses, with information placed on the web and public comment sought before the application can proceed.

The new legislation replaces a voluntary program, and while the scientific community appeared to be abiding by the old program, Di Marco said there was no provision for enforcement.

Nevertheless, in some industry quarters, the Act has raised concerns about intellectual property rights.

"It will be interesting to see how the Gene Technology Regulator balances the need to make information publicly available with the need to keep commercially sensitive information secret," Di Marco said.

She noted in the months following the Act's commencement, companies were unsuccessful in their application to the Regulator to keep the location of genetically modified crop trials secret.

too early

Tony Coulepis, executive director of AusBiotech, the peak body for the Australian biotechnology industry, said it was still too early to evaluate the Act fully.

"Often you find the devil is in the detail and a lot of (the Act's) details have not been tested yet," Coulepis said.

But, he added, "we now have a process and framework for ethical progress. I don't think there's anyone in the industry that doesn't welcome that."

The Act requires the Regulator to make a decision on an intentional release application within 170 business days of receiving the initial application; for non-release applications, the period is 90 days. However, "time is being flagged as a potential issue," Coulepis said, with some sectors of the industry "cautious" about the Regulator's ability to make a decision within the required period.

He was less concerned about the question of disclosing sensitive business information, noting that businesses already have to make frequent disclosures to regulators.

"But again, the devil is in the detail," he said.

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Genetic science forums show interest in NT

A small but enthusiastic turn-out voiced their opinions at the NT public meetings on human genetic information in March.

Hosted by the Australian Law Reform Commission and Australian Health Ethics Committee, the public meetings were part of an Australia-wide consultation process for the national genetic inquiry.

The ALRC and AHEC are investigating, in relation to the use of human genetic samples and information, how best to:

- protect privacy;
- ensure protection from unfair discrimination; and
- ensure high ethical standards of control.

While in Darwin, Professor David Weisbrot from the ALRC and Reverend Bill Uren also met with the Law Society, NT police, Menzies School of Health Reasearch and various other government departments.

In Alice Springs, they also met with Aboriginal leaders and legal aid services.

The public meetings were held in both Darwin and Alice.

The inquiry is due to release a discussion paper in August which will outline the issues and propose findings for reform in the area of genetic technology and information.

The proposed date for the final paper is March next year.

Those interested in further information or making a comment about the issue can go to the website: www.alrc.gov.au, email genetic@alrc.gov.au, phone (02) 9284 633.