The Japan Society of Obstetrics and Gynecology ban genetic diagnosis of embryos before implantation under its 1998 guidelines. It is until recently that this measure raises opposition. Doctors and patients demanded the society ¥77 million (US$700,700) for severely restricting opportunities for such diagnosis. The case was brought up to court on 29 July.

The plaintiffs for the case are Tetsuo Otani of Otani Women's Clinic in Kobe, Yahiro Nezu of Suwa Maternity Clinic in Nagano, and five couples claim to need the diagnosis. Naoya Endo, chief attorney for the plaintiffs, said, "The society claims that the diagnosis is still at a stage of clinical research, but there have already been more than 1,500 cases (of diagnosis) carried out worldwide. Our patients are really waiting (to have the diagnosis performed)."

Pre-implantation genetic diagnosis in done by checking parts of the human egg cell fertilized in vitro. The purpose is to spot out any defects or illnesses in the upcoming fetus, especially for those with a hereditary record of illness. Eggs found to have such problems will not be implanted in the womb.

The society prohibits any pre-implantation diagnosis except for prevention of serious and incurable genetic diseases. Such cases have to be submitted to the society for approval. It was only on July 24, that the first case had been approved for a couple to have the diagnosis done in Keio University. The diagnosis is carried out to determine whether the baby would have Duchenne muscular dystrophy, a malignant disease.

Endo said the diagnosis is already carried out in most countries, it is time for the society to nullify the guidelines. Four out of the five couples in the suit said they need the diagnosis because of chronic miscarriages, while the fifth couple has a genetic disease that pass into their next generation. Endo urged that the lift of the ban could avoid these problems and already a 2,500 people have signed a petition supporting the lift.

In reply, the society submitted a document saying the Constitution does not guarantee the right to pick and choose the lives of embryo. It also suggested that this is a highly ethical question, which should be settled through legislative measures, but not a judicial decision. The statement of the society criticizes that loosening the restrictions could lead to discrimination based on disabilities, genetic disorders or even sex selection.

Dr Otani, one of the plaintiffs, performed the diagnosis earlier to determine the sex of the eggs before implantation for his patients. The society said it is "an act far from being called medical treatment" and a "denial of human dignity". Otani said his actions "serve the public amid the current declining birthrate" as it could encourage people to have more children.

The plaintiffs also said the society already accepted prenatal diagnosis of embryos, like amniotic fluid screenings and ultrasound diagnoses, to provide information like sex and health of the babies to the parents. They suggested the new diagnostic method is even better to protect the mother, as it does not require abortion if the baby is indeed bearing genetic disease or has the wrong sex.
Amendments to Australian IP law with the US FTA

I P Australia has recently examined the impact of Australia-US Free Trade Agreement (FTA) on the intellectual property laws of the country, several amendments to the existing regulations will be made.

Mark Vaile, Australia’s Minister for Trade, introduced the US FTA Implementation Bill 2004 into the Australian Parliament on 23 June 2004. Most of the provisions in the Bill are expected to commence on the later of 1 January 2005 or the day on which the AUSFTA comes into force. The Bill has nine schedules, in which schedules 2, 3, 7, 8 and 9 make amendments to legislation resulting from the obligations under chapter 17 – the IP Chapter of the Agreement.

Schedule 7 and 8 is particularly important to the pharmaceutical industry. It is stated in schedule 7 that an applicant seeking to include therapeutic goods in the Australian Register of Therapeutic Goods will need to provide one of two certificates. They should either certify that they do not propose to market those therapeutic goods in a way or in circumstances that would infringe a patent, or that they propose to market the therapeutic goods while a relevant patent is in force and that they have notified the patent owner of their application to include goods in the Register.

There has been a great deal of concern that the FTA will delay generic drugs from entering the market. The amendments from schedule 7 represent a careful balance between the interests of the generic and innovator pharmaceuticals in Australia and give the patent owner no additional rights to intervene a generic company seeking marketing approval.

The current grounds for revocation in the Patents Act are broader than the grounds on which the grant of a patent can be refused. In schedule 8, the two grounds are made to align with each other. The grounds upon which the grant of a patent can be opposed (or refused) will be extended to include the situations that the invention is not useful, or was secretly used and thus retain these as grounds upon which a patent may be revoked.

The biggest opposition to the FTA has been based on the possibility that it will delay the entry of generic medicines into the Australian market and encourage the evergreening of patents. IP Australia said that many of the comments and concerns in this aspect appear to arise from people looking at this provision in light of US practice rather than considering the actual text of the AUSFTA. It is said that the text of Article 17.10.4 was specifically crafted in such a way that Australia has the flexibility to implement this obligation in a way which best suits the Australian system, rather than being forced to adopt the US approach.

For evergreening, IP Australia is not going to make any changes to the type of inventions that can obtain patents protection. Australia is not required by the AUSFTA to change its existing patent extension regime, thus patent owners will not be able to extend the term of their patents beyond what they can do under existing arrangements.

The AUSFTA has provoked a heated debate between the cabinet led by John Howard and the Australian Labor Party led by Mark Latham, in which the latter suggested that the benefits of local industries would be affected from the agreement. The target date for the Agreement to enter into force is 1 January 2005.