



## Dolly Goes to Market

### World Patents on Sheep Clones Include Humans

While the entire world was caught up in the scientific excitement and ethical conundrums created by the cloning of sheep late last February, few noticed that Dolly's inventors had applied for patents covering the cloning technology. As the world debated the brave new world of medical advances and risks implicated in the cloning achievement, a few watched to see if the patents - if granted - would encompass all mammals - or deliberately exclude human beings. "The worldwide patents are now out - and we're in," Edward Hammond of RAFI observes. "This isn't just a mutton monopoly, the patents cover everything that crawls, flies, swims, walks or talks," he adds. "The issue is never just the science," RAFI's Jean Christie continues, "its who owns and controls the technology."

**Patents Out - People In:** The twin patents were granted under a convention of the World Intellectual Property Organization (WIPO) - a United Nations agency headquartered in Geneva. Patents No. WO 97/07668 and WO 97/07669 were published on March 6, just a few days after the world learned of the cloning success. RAFI has since been working to determine the legal scope of the patent claims and the degree to which the world's major patenting jurisdictions have agreed to the patents. "The applications covered virtually every country that has a patent system," Hammond says, "Most patent offices would have accepted Dolly without even knowing the implications."

To confirm that the patents include human beings, RAFI contacted both the Scotland-based Roslin Institute, and PPL Therapeutics, the company established by Roslin to commercialize its research. Although Dolly's "inventors" are adamant that they have no commercial interest in - and no moral tolerance of - human cloning, Roslin Institute confirms that the patents cover all animals, including humans. While some other biotech companies, confronted with similar ethical concerns, have worded their patents to specifically exclude humans, the Roslin patents deliberately make no such exclusion. Asked why, the Institute told RAFI that the inclusion of humans would ensure that nobody else could lay claim to human cloning and thus Roslin would try to ensure that humans would not be cloned.

**Pulling the Wool over ...?** RAFI does not question the sincerity of the Institute's intentions. However, RAFI's Hope Shand points out, "The ethics and fate of human cloning is not a matter to be entrusted to the Roslin Institute. This is an issue of profound global importance and must be resolved at the highest levels."

The Roslin Institute has agreed to give an exclusive license to PPL Therapeutics for the production of therapeutic proteins in the milk of genetically modified animals. PPL is a small biotech company with offices in the UK and the USA. According to PPL Managing Director, Ron James, "We're still talking to them [Roslin] about other licensing uses and I expect that others are talking to them as well." Depending on the conditions of licensing agreements, PPL or other companies could be well within their rights to develop human cloning and/or to sub-license other companies to pursue this research opportunity. PPL has research agreements with three major pharmaceutical enterprises with interests in human therapeutics. "Behind the

Roslin Institute is PPL," Shand reports, "but behind PPL are Boehringer Ingelheim of Germany, Novo Nordisk of Denmark, and American Home Products of the US. These are very large players in the life industry. In particular, Boehringer Ingelheim is actively collaborating with human genomic companies.

Edward Hammond of RAFI notes that the patent gives exclusive monopoly over the cloning of all animals - not excluding humans - until at least 2017. "Some of the inventors could expire before the patent does," Hammond warns.

**No "Silence of the Lambs":** RAFI will fight the Dolly patents. This weekend, Edward Hammond will fly to Geneva to attend the Assembly of the World Health Organization (WHO). The UN body has already resolved to oppose human cloning but Hammond hopes to encourage government delegations to also call for the revocation of the two patents in each country. RAFI is also pressing for the WHO to tighten its guidelines covering the ethics of medical research. While in Geneva, Edward Hammond will also visit WIPO and the World Trade Organization to investigate means by which the patents could be disallowed under a rarely-used "*order public*" ("public morality") clause in the World Trade Agreement.

Meanwhile, RAFI's Executive Director, Pat Mooney, will fly to Rome to meet with officials of the UN Food and Agriculture Organization (FAO) to discuss the impact of livestock cloning on animal diversity. "The patent implications are not just for people but for animal genetic resources as well," Mooney states. "The immediate impact may be felt on the farm and steps must be taken to ensure that cloning does not destroy breed diversity. We are losing livestock breed diversity at the rate of 5% per year." he adds, "Cloning could make the situation much worse. We need to retain our genetic options in order to confront both new diseases and new opportunities."

**Dolly Goes to Court:** Finally, RAFI will take the Dolly patents issue - along with a number of other specific patent concerns - to a Special Session of the UN General Assembly from June 23-27 in New York. "The Dolly patents are only the most recent of a number of instances where patent monopolies threaten public morality," Jean Christie asserts. "We are hoping that the General Assembly will agree to ask the World Court (the International Court of Justice at The Hague) for an advisory opinion. The Court's views could significantly affect the work of WIPO and the World Trade Organization."

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**About RAFI:** The Rural Advancement Foundation International is an international non-governmental organisation headquartered in Ottawa, Ontario (Canada) with an affiliate office in Pittsboro, North Carolina (US). RAFI is dedicated to the conservation and sustainable improvement of agricultural biodiversity, and to the socially responsible development of technologies useful to rural societies. RAFI is concerned about the loss of genetic diversity - especially in agriculture - and about the impact of intellectual property rights on agriculture and world food security.