



“INTELLECTUAL PROPERTY LAWS IN THE CONTEXT OF BIOTECHNOLOGY INDUSTRY IN MALAYSIA”

Presentation by
Associate Prof. Rohazar Wati Zuallcoble
Deputy Director General (Industrial Property) MyIPO
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IP ECO-SYSTEM

- CREATION
- PROTECTION
- INNOVATION
- COMMERCIALIZATION



The Role of MyIPO

- Supporting government aspiration.
- “Malaysian National Biotechnology Policy 2005”
- Malaysia a “mega-diversity” country.
- Ratification to CBD.
- Funding under 9th Malaysia Plan.
- MBC.



Managing IPR In MyIPO

1) Copyright

2) Industrial Property:-

Patent

- Trade Marks
- Industrial Designs
- Geographical Indications
- Layout Designs



The IPR legislation

- The Copyright Act 1987
- The Patent Act 1983
- The Trade Marks Act 1976
- The Industrial Designs Act 1996
- The Geographical Indications Act 2000
- The Layout Designs of Integrated Circuit Act 2000.



International Obligations

- The International treaties and Convention.
 - - Berne Convention.
 - - Paris Convention.
 - - TRIPS Agreement.
 - - PCT
- Coming:
 - Budapest Treaty
 - WCT/WPPT



Managing Patent at MyIPO

- Receiving patent application and fees
- Examination as to form
- Publication of the application
- Examination as to substance
- Refusal or grant
- Maintenance of patents



Additional Services For Patent

- Application For Compulsory Licenses.
- Patent Information Services.
- Update The Policy And Legal Aspects Of Patent Law.
- Supervise Technical Training For Patent Inspection Officers.
- Monitor Registration And Renewal Of Patent Agents.



IP for Biotechnology

- No restriction.
- Protection from creation to commercialization.
- The route of protection:-
 - Patent
 - Confidential information
 - Industrial designs
 - Trade marks



Patent for Biotechnology

- TRIPS Article 27 (1) “ Patent shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application”



Malaysian Patent Act 1983

- There is no express prohibition or exclusion of patenting of biotechnology.
- The express prohibition for patent are those exclusion in section 13 of Patent Act 1983.



Important Exclusion

- Exclusion from patentability of plants and animal varieties and of essentially biological processes for the production of plants and animals, other than man-made living micro-organisms, micro-biological processes and the products of such micro-organism processes.
- Section 13(1)(b).



Exclusion for Treatment

- Method for treatment of human or animal body by surgery or therapy, and diagnostic methods practiced on the human or animal body other than to products used in any such methods.
- Section 13(1) (d).



Public Order and Morality

- Section 31 “ The grant of patent shall not be refused.....except where the performance of that act would be contrary to public order or morality.



The human-sheep chimera has 15 per cent human cells and 85 per cent animal cells. — DM picture

World's first sheep with half-human organs

LONDON: Scientists have created the world's first human-sheep chimera — which has the body of a sheep and half-human organs.

The sheep has 15 per cent human cells and 85 per cent animal cells — and its evolution brings the prospect of animal organs being transplanted into humans one step closer.

Professor Esmail Zanjani, of the University of Nevada, has

spent seven years and £5 million (RM33.5 million) perfecting the technique, which involves injecting adult human cells into a sheep's foetus.

He has already created a sheep liver which has a large proportion of human cells and eventually hopes to precisely match a sheep to a transplant patient, using their own stem cells to create their own flock of sheep.

The process would involve extracting stem cells from the donor's bone marrow and injecting them into the peritoneum of a sheep's foetus.

When the lamb is born, two months later, it would have a liver, heart, lungs and brain that are partly human and available for transplant.

At present, 7,168 patients are waiting for organ transplant in Britain, and two-thirds are ex-

pected to die before an organ becomes available.

Scientists have applied to the government's fertility watchdog for permission to start work on the chimeras.

But the development is likely to revive criticisms about scientists playing God, with the possibility of silent viruses, which are harmless in animals, being introduced into the human race. —DM



Ethical and moral issues

- Relationship between inventions and living matter.
- - processes for cloning human beings;
- - processes for modifying the germ line genetic identity of human beings;
- - uses of human embryos for industrial or commercial purposes;
- - processes for modifying the genetic identity of animals which are likely to cause them suffering any substantial medical benefit to man or animal and also animals resulting from such processes.



Application for patent

- All criteria for patentability must be met:-
 - - novelty
 - - inventive step
 - - industrial application.
- Procedural requirement:-
 - ‘disclosing biotechnology invention in the description’



When Drawing Is Not Adequate

- Deposits of microorganism
- Via IDA
- The Budapest Treaty
- Not possible at the office.
- Via modified examination



MyIPO Initiatives

- Accession to Budapest treaty
- National Depository Authority
- A Joint-Committee on Policy for Patenting of Biotechnological inventions.
- Guide-line for Patent Examiner
- Training and coaching of patent examiner with foreign IP office on biotechnology.



TK and GR

- Bio-prospecting
- Bio-piracy
- TRIPS new provision “ to facilitates access and benefit sharing ”



Article 29 bis

- Proposed text “Where the subject matter of a patent application concerns, is derived from or developed with biological resources and/or associated traditional knowledge.....Members shall require applicants to disclose.....”
- Prior informed consent for access and fair and equitable benefit sharing arising from the commercial or other utilization of such resources.....



Implications to the IP Office

- Members shall put in place effective enforcement procedures to ensure compliance with this obligations.....
- Members shall ensure that administrative and/or judicial authorities have the authority to prevent the further processing of an application or the grant of a patent and to revoke.....or render unenforceable the patent.....





Biotechnology Patent Applications

- Local application
 - - rubber industries
 - - food
 - - palm oil.
- Foreign application
 - - food
 - - pharmaceuticals
 - - medicines



Patent Application Received And Granted For Year 1986 To Year 2007

YEAR	PATENT APPLICATION			Pending			Clear Exam	To Grant	Refused	Withdrawn	Grant & Post Grant	Others	TOTAL
	LOCAL	FOREIGN	TOTAL	Formality	Substantive Exam To Do	Further Examination							
1986	28	234	262	0	0	0	0	0	40	24	198	0	262
1987	72	3,199	3,271	0	0	0	2	0	262	363	2,644	0	3,271
1988	75	1,546	1,621	0	0	0	1	1	233	172	1,213	1	1,621
1989	83	1,802	1,885	0	0	0	3	0	344	222	1,316	0	1,885
1990	92	2,212	2,304	0	0	0	6	0	388	313	1,597	0	2,304
1991	109	2,325	2,434	0	1	8	24	6	471	381	1,543	0	2,434
1992	152	2,262	2,414	0	1	20	61	2	539	334	1,457	0	2,414
1993	202	2,682	2,884	0	1	21	42	4	654	424	1,738	0	2,884
1994	228	3,365	3,593	0	3	11	76	4	1,096	486	1,917	0	3,593
1995	183	3,982	4,165	0	1	14	142	7	1,214	753	2,034	0	4,165
1996	219	5,354	5,573	0	4	26	496	10	1,567	1,156	2,314	0	5,573
1997	181	6,265	6,446	0	3	59	383	27	1,762	1,457	2,755	0	6,446
1998	191	5,778	5,969	0	1	76	405	31	1,619	1,360	2,477	0	5,969
1999	215	5,624	5,839	0	1	106	316	26	1,413	1,411	2,566	0	5,839



YEAR	PATENT APPLICATION			Pending			Clear Exam	To Grant	Refused	Withdrawn	Grant & Post Grant	Others	TOTAL
	LOCAL	FOREIGN	TOTAL	Formality	Substantive Exam To Do	Further Examination							
2000	202	6,030	6,232	0	4	241	448	38	1,370	1,746	2,385	0	6,232
2001	269	5,679	5,948	1	28	707	418	75	1,063	1,733	1,923	0	5,948
2002	325	4,609	4,934	263	53	1,199	345	121	723	1,025	1,204	1	4,934
2003	377	4,676	5,053	627	456	2,229	352	80	306	591	412	0	5,053
2004	513	4,929	5,442	1,029	2,983	581	67	24	91	523	144	0	5,442
2005	514	5,770	6,284	2,815	3,052	28	22	2	39	299	27	0	6,284
2006	527	4,286	4,813	4,092	679	10	3	0	17	12	0	0	4,813
2007	401	1,191	1,592	1,291	283	1	0	0	16	0	0	1	1,592
TOTAL	5,158	83,800	88,958	10,118	7,554	5,337	3,612	458	15,227	14,785	31,864	3	88,958



Statistik Penerimaan Form 5/5A dan Deferment F5B Tahun 2003 hingga 2006

Tahun	Pending Formality	Form 5/5A	Form 5B
2003	3,282	2,551	1,558
2004	5,126	3,289	1,972
2005	6,170	1,335	1,416
2006	4,676	624	658
Total	19,254	7,799	5,604



Summary of Biotechnology Application

Patent Biotechnology Application and Granted From 1986 to 2 March 2007

Patent Application received from 1986 to 2007	87,343
Granted Patent Biotechnology from 1 October 1986 to 2 march 2007	
Malaysia	5
Foreign Country	357
Pending Patent Biotechnology from 1 October 1986- 2 March 2007	1,573



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<http://www.myipo.gov.my>

THANK YOU