

STEM CELL RESEARCH DEVELOPMENT AND ITS PROTECTION IN INDONESIA*

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Abstract

This research discusses the possibility of patenting stem cells under the Indonesian patent law by focusing on two essential issues: (a) what approaches should be chosen by the Indonesian government to protect stem cell research under the Indonesian Patent Act and non-patent regulations? and (b) what types of stem cells can be protected under the Indonesian Patent Act? In order to provide comparative perspectives, this paper discusses the experience and policies of the US, German and South Korean governments in protecting stem cell research under their patent acts.

Keywords: *patent law, stem cell research and stem cell patents.*

Intisari

Penelitian ini mendiskusikan kemungkinan mematenkan sel punca dalam hukum paten di Indonesia dengan memfokuskan pada dua isu pokok: (a) Pendekatan apa yang sebaiknya dipilih oleh pemerintahan Indonesia untuk melindungi penelitian sel punca dalam hukum paten Indonesia dan peraturan non paten? (b) Tipe sel punca apa yang dapat dilindungi dalam hukum paten Indonesia? Untuk mencakupi pendekatan melalui perbandingan dengan luar negeri, penelitian ini membahas pengalaman dan kebijakan di pemerintahan AS, Jerman, dan Korea Selatan dalam melindungi penelitian sel punca dalam hukum paten masing-masing negara.

Kata Kunci: hukum paten, sel punca, penelitian dan hukum paten sel punca.

Pokok Muatan

A. Background	387
B. Research Methods	388
C. Results and Analysis	389
1. Stem Cell Research Development and Regulations in Indonesia.....	389
2. The Indonesian Patent Act: An Overview	391
3. The Future of the Indonesian Stem Cell Patents Regulations and the Possibility of Adopting Stem Cell Patent Regulations and Policies in the USA, Germany and Korea. ...	394
4. The Types of Stem Cells Should be Protected by the Indonesian Patent Act.....	399
D. Conclusions.....	400

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A. Background

Even though there is no single definition for stem cells, scientists agree that stem cells are unique, with different types of cells¹ and special properties enabling them to regenerate body parts, such as cells, tissues, and organs.² With those unique characters, stem cells have become alternatives to cure chronic, degenerative and acute diseases and to improve pharmaceutical development through more effective drug testing. They can also repair damaged tissue and construct tissue structures and organs.³

In general, stem cells can be classified as embryonic stem cells and non-embryonic stem cells (adult stem cells). These bring different consequences to human beings. Embryonic stem cells have been controversial due to moral issues.⁴ This is because this type of stem cells might destroy or kill embryos during the process of obtaining stem cells. Unlike embryonic stem cells, adult stem cells do not use embryos and they can be obtained through umbilical cords.⁵

In the United States, adult stem cells have been proven to be beneficial for curing particular diseases, such as diabetes, fatal skin disorder,

faulty immune systems, stroke, brain and nerve injuries. Furthermore, according to new research in the UK, “the adult cells were more effective than cells from aborted babies.”⁶

Supported by advanced medical technologies, stem cells undeniably bring new hope to human beings, and are very suitable for development in the Indonesian public health sector. In 2000, stroke, heart disease and diabetes were among the top seven non-communicable diseases causing the highest numbers of deaths in Indonesia.⁷ To maximize the use of stem cells and to protect Indonesian consumers, the Indonesian Health Ministry has published regulations on stem cells. A public hospital in Jakarta, Cipto Mangunkusumo, has trialled stem cell use in about 700 clinical cases of acute heart disease and diabetes. The government is also planning to build public umbilical cord bank to develop stem cell research in Indonesia.⁸ All of these activities require a patent system. The patent system provides exclusive rights to inventors of stem cell products. Under these rights, the creativity of a scientist’s work is protected by law, providing an incentive for him or her to continue doing research and inventing

¹ Tam Wai Leong and Lim Bing, “Embryonic Stem Cell Research: Prometheus Revisited” in Terry Kaan & Edison T Liu, 2006, *Life Sciences: Law and Ethics, Recent Developments in Singapore*, Singapore Academy of Law and Bioethics Advisory Committee Singapore, Singapore, p. 36.

² Junying Yu & James A. Thomson, “Regenerative Medicine Report”, <http://stemcells.nih.gov/info/2006report>, retrieved on 07 September 2010; David E. Newton, 2007, *Stem Cell Research*, Facts On File Inc., New York, p. 5-6; B.H. Frazier, 2009, *New Perspectives on Human Embryonic Stem Cell Research: What You Need to Know About the Legal, Moral and Ethical Issues*, Vandepias Publishing, Lake Mary, Florida, p. 78; Henrik Jorgensen & Anne Lykkeskov (eds.), 2005, *The Ethics of Patenting Human Genes and Stem Cells*, The Danish Council and Ethics, Copenhagen, p. 52; *Ibid.*, p. 48.

³ Tam Wai Leong and Lim Bing, *supra* note 1, at 37; Justine Burley, “An Abstract Approach to the Regulation of Human Genetic: Law, Morality and Social Policy”, in Han Somsen, 2007, *The Regulatory Challenge of Biotechnology: Human Genetics, Food and Patents*, Edward Elgar Publishing Limited, Cheltenham UK, p. 64; Peter Wiedemann, Judith Simon, Silke Schick Tanz & Christof Tannert, “The Future of Stem-Cell Research In Germany – A Delphy Study”, EMBO Reports, <http://www.nature.com/emborjournal/v5/n10/full/7400266.html>, retrieved on 08 September 2010; Bryn E. Floyd, “Regulation of Stem Cell Research: A Recommendation that the United States Adopt the Australian Approach”, 13 (1) *Pacific Rim Law & Policy Journal*, 38, 2004.

⁴ SNAP (Stem Cell Network Asia Pacific), <http://asiapacificstemcells.org/members/Indonesia.aspx>, retrieved on 05 September 2010.

⁵ Pusat Riset Biomedik (CEBIOR) FK UNDIP, “Harapan Baru Pengobatan Sel Punca di Indonesia (A New Hope on the Stem Cell Therapy)”, <http://www.id.cebior.co.cc/index.php?option=comcontent&task=view&id=22&Itemid=1>, retrieved on 06 September 2010.

⁶ Bradley Mattes, “Embryonic Versus Adult Stem Cells? It’s Really No Contest”, <http://www.lifeissues.org/cloningstemcell/bradsarticle.html>, retrieved on 29 October, 2012.

⁷ The Embassy of India in Jakarta, “The Market for Pharmaceutical Products and Materials in Indonesia”, http://www.embassyofindiajakarta.org/Pharmaceutical_mkt_survey.pdf, retrieved in July 2004, p. 78; Depkes RI (The Ministry of Health), “Profil Kesehatan Indonesia 2001 (The Indonesian Health Profile 2001)”, <http://www.depkes.go.id/download/Narasi2001.pdf>, retrieved in 2002, at. 48, see also Caroline Sardjono, *et al.*, “Application of a Modified Method for Stem Cell Isolation from Lipoaspirates in a Basic Lab”, 18 *Medical Journal of Indonesia*, 95, 2009, see also Carmel Shalev, “Access to Essential Drugs, Human Rights and Global Justice”, in Felix Thiele & R.E. Ashcroft, 2005, *Bioethics in a Small World*, Springer-Verlag, Berlin, p. 99.

⁸ Media Indonesia, “Berharap Secara Wajar Kepada Stem Cell” (Realistic Hoping to Stem Cells), Wednesday, *Media Indonesia Newspaper*, 14 October 2009, p. 19.

new stem cell products.⁹ The problem is that Indonesia, a developing country, has taken a step towards banning the patenting of animal and human cloning under Article 7 (a and d.i) of the Indonesian Patent Act. In the general elucidation of the law, it is stated that the purpose of Article 7 is to accommodate public opinion, which is largely against the patentability of living organisms (plant, animal and human). Indonesia prohibits it on the basis of morality and ethical issues. Even though human stem cells are not explicitly mentioned in Article 7 and its elucidation, its interpretation could include stem cells. It is understandable that stem cells are often connected to ethical issues as the process of obtaining stem cells destroys human embryos.¹⁰

This research discusses the possibility of patenting stem cells under the Indonesian patent law. It will focus on two issues: a) what approaches should be chosen by the Indonesian Government to protect stem cell research under patent law and non-patent regulations? and b) what types of stem cell research can be protected by the Indonesian Patent Act?

It is important to answer these questions because there has been no systematic and comprehensive legal review of the possibilities for protecting stem cell research in Indonesia. This paper also describes the experience and policies of the USA, Germany and South Korean governments in protecting stem cell research. Such information will help the Indonesian government to consider several policies dealing with the protection of stem cell research under a patent system and non-patent regulations in the future.

B. Research Methods

This research will be a valuable resource for the Indonesian government in two areas:

First, the research analyzes the impact of patents on the development of stem cell research in Indonesia. It is hoped that the research will encourage the government to develop and apply appropriate strategies and policies that maximize the benefits of the patent system and the development of stem cell research in Indonesia.

Second, this research reinforces the capacity for government decisions to seek a balance between patent protection and the development of stem cell research for the purpose of public welfare by taking lessons from other countries' experiences, particularly, the USA, Germany and Korea.

This sociolegal research included both field data collection and desk-based research. Interviews were conducted with Indonesian experts from Directorate General of Intellectual Property, the National Agency for Food and Drug Control (NA-FDC), the Stem Cell and Cancer Institute, Faculty of Medicine University of Indonesia and Faculty of Medicine at the University of Airlangga. Library-based research was conducted at the Max Planck Institute in Munich, Germany, and libraries in Jakarta, including at the Ministry of Health, the National Agency for Food and Drug Control (NA-FDC) and the Directorate General of Intellectual Property Rights.

Raw data was analyzed qualitatively using logical thinking, logical analysis, deductive and inductive analysis, analogy, and comparison. These means allowed examination of all research variables and providing an accurate picture of the development of stem cells and the possibility of protecting stem cells under the Indonesian Patent Act and national laws.

⁹ See Joseph Straus, "Patenting of Human Genes and Human Gene Therapy", in Hans-Peter Bernhard & Clive Cookson, 1995, *Genetics: Debating Issues and Ethics in Genetic Engineering*, Ciba-Geigy Limited and Chiba Communications, Basel Switzerland, p. 50-52; see also Helen Torgersen *et al.*, "The Framing of A New Technology: 1973-1996", in Martin W. Bauer & George Gaskel, 2002, *Biotechnology-The Making of a Global Controversy*, Cambridge, London. 2002, p. 71-72.

¹⁰ Diane T. Duffy, "Background and Legal Issues Related to Stem Cell Research", CRS Report to Congress Received through the CRS Web (Order Code RS21044 Updated June 12, 2002, pp. 1-2; David E. Newton, *supra* note 2, at 3-4.

C. Results and Analysis

1. Stem Cell Research Development and Regulations in Indonesia

a) Development of Stem Cell Research in Indonesia

Stem cells have been used in Indonesia since 1978 for bone transplants and to cure cancer by aggressive chemotherapy.¹¹ A number of teaching hospitals in Indonesia have conducted, and continue to conduct, research on stem cells, with different standard operating procedures depending on the capabilities of the hospital. The target of most stem cell research in Indonesia is to produce stem cells that can be used in cases of stroke within the next 3-5 years. To achieve this goal, research also uses animals.¹²

According to Boenjamin Setiawan, a member of the Board of Trustees of the Indonesian Stem Cell Association, the number of teaching hospitals conducting stem cell research in Indonesia is increasing. In Jakarta, the Faculty of Medicine at the University of Indonesia (FK-UI) and its teaching hospital, Cipto Mangunkusumo Hospital (RS Ciptomangunkusumo/RSCM) is developing stem cells for treating cancer, second-degree burns, diabetes, liver disease and orthopedic problems. In 2006, the Stem Cell and Cancer Institute was established to start conducting research on Endothelial Progenitor Cells (EPC), SCNT, antioxidants for EPC, second-degree burns, chronic burns, AMI, Critical Limb Ischemia (CLI) and bones. Other universities, such as Bogor Institute of Agriculture (IPB), Padjajaran University (UNPAD), Maranatha Christian University (UKM), Universitas Gadjah Mada (UGM), Hasanuddin University (UNHAS), Bandung Institute of Technology (ITB), Brawijaya

University (UB) and Airlangga University (UNAIR), are also developing stem cells for treating partheno, pancreatic disease, CLI, second-degree burns, arthropedics, arterial disease, lever, Acute Myocardial Infarction (AMI) dan EPC.¹³

Based on a 2009 RISTEK (Research and Technology) survey on institutional capacity and capability, centers considered capable of performing stem cell research in Indonesia were: (1) the Institute for Tropical Diseases (ITD) Airlangga University (UNAIR), (2) the Integrated Stem Cell Installation Unit, at the University of Indonesia Faculty of Medicine (FKUI-RSCM), (3) Stem Cell and Cancer Institute (SCI) Kalbe Farma, and (4) the Embriology Laboratory, Anatomy and Physiology, Faculty of Veterinary Science, Bogor Institute of Agriculture (IPB).¹⁴

The Institute of Tropical Disease, Airlangga University, Surabaya and the Biomaterial Center-Tissue Bank at Dr. Soetomo General Hospital/ Medical School of UNAIR, Surabaya are developing stem cells for application in bone, cartilage, and tendon engineering.¹⁵ According to Dr. Ferdiansyah, SpOT, the process of obtaining stem cells depends on the types of stem cells. In general, it takes 12 days to 21 days.¹⁶

b) Non-Patent Regulations on Stem Cell Research in Indonesia

Even though stem cell research is still quite new for the majority of Indonesians, the Indonesian government has made efforts to regulate their use. Three regulations cover stem cell research:

1) Act No. 36 of 2009 on Health.

Act No. 36 of 2009 on Health was enacted on September 14, 2009. The act amended the previous Health Law (the Act No. 23 of 1992),

¹¹ The Health Minister Decree No. 834/MENKES/SK/IX/2009 on the Guidelines on the Implementation of Medical Stem Cell Service, p. 5.

¹² *Ibid.*

¹³ Teknopreneur, "Antara Sel Punca, Etika, dan Pemerintah" (Between Stem Cells, Ethics and Government), <http://www.teknopreneur.com/content/antara-sel-punca-etika-dan-pemerintah>, retrieved on 6 September 2010.

¹⁴ RISTEK Website, "Pengembangan Teknologi Sel Punca di UNAIR Surabaya Membanggakan" (The Development of Stem Cell Technology at Airlangga University Is a Proud Achievement), <http://www.ristek.go.id/?module=news%20News&id=5392>, retrieved on 06 September 2010.

¹⁵ SNAP (Stem Cell Network Asia Pacific), <http://asiapacificstemcells.org/members/Indonesia.aspx>, retrieved on 05 September 2010.

¹⁶ Interview with Ferdiansyah, a researcher on stem cells from Dr. Sutomo Hospital, Surabaya on October 6, 2012.

which was considered out of date as it did not cover the latest developments in science and medical technology.¹⁷ The broad-ranging act regulates all aspects of the public health sector, such as the rights and obligations of patients and health providers, increased public funding for the public health sector, regulations on cigarettes and smoking in public areas, provisions on abortion, and other health issues. Even though the act deals with public health in general, it also consists of provisions on stem cells, such as Articles 64, 66, 70 and 75.

Article 64 provides the legal basis for using stem cells to cure particular diseases and allows cell transplantation if it is clinically safe for the patient (the Article 66). The most important provision in the Law on Health, however, is Article 70 Par. 2. According to this article, embryonic stem cells cannot be used to cure patients' diseases in Indonesia. Aside from a few limited exceptions, abortions are not allowed in Indonesia. This provision seems parallel to a provision that bans the use of embryonic stem cells.

2) Health Ministry Regulation No. 833/MEN-KES/PER/IX/2009 on the Implementation of Stem Cell Services

This regulation, which consists of 21 articles, was launched by the Ministry of Health on September 11, 2009. In publishing the regulation, the government recognized that with the rapid development of science and medical technologies, stem cells were becoming increasingly important for curing degenerative and genetic diseases. Second, through the regulation, the government attempted to ensure the rights of patients or stem cell users would be protected so that better services could be provided in the public health sector.

In this regulation, stem cells are defined in general terms, including definitions of non-embryonic stem cells and stem cell banks. Unlike the Law on Health, the Health Ministry Regulation does not specifically state the type of stem cells

that can be used by patients. Rather, it focuses more on the hospitals eligible to participate in the implementation of stem cell treatments, based on government standards (Article 5). It also includes provisions on the storage of stem cells by stem cell banks in hospitals or outside of hospitals (Article 6).

Further, Article 10 stipulates that only teaching hospitals that fulfil the requirements for implementing stem cell services, such as possessing stem cell installation facilities, a stem cell bank, an integrated research facility, stem cell experts and a special unit for stem cell service installation, are eligible for implementing stem cell treatments. Even though the regulation does not specifically mention the types of degenerative and genetic diseases able to be treated, Article 13 stipulates that the use of stem cells in Indonesia is confined to diseases where an evidence base for the use of stem cells exists. The regulation also encourages research and development, but stipulates that eligible hospitals will be appointed by the minister of health in coordination with its bioethics unit, hospital medical committees and the national research agency (Article 16). The article also allows the exportation and importation of stem cells following obtaining a license from the Ministry of Health.

In order to ensure stem cell research in Indonesia is sustainable, the regulation states that it is necessary to establish a national stem cell committee consisting of representatives from the Ministry of Health, the National Education Ministry, related professional associations, hospital associations, a national bioethics committee and other experts (Article 18).

3) Health Ministry Decree No. 834/MEN-KES/SK/IX/2009 on Guidelines for the Implementation of Medical Stem Cell Services.

The Health Ministry Decree on Guidelines for the Implementation of Medical Stem Cell

¹⁷ PT Phapros, "UU Kesehatan 2009, Pemenuhan Hak Masyarakat atas Kesehatan" (Health Act 2009: a Fulfillment of People Rights on Health), <http://www.ptphapros.co.id/article.php?&m=Article&aid=97&lg=>, retrieved on 13 September 2010.

Services plays an important role in regulating stem cell use because it consists of detailed and specific procedures. This is intended to give practical instructions to stem cell service providers, particularly the teaching hospitals that fulfill government requirements and standards. The guidelines cover a broad range of issues, from the background and purpose of the guidelines, to legal basis, targets, stem cell definitions, organizational structures and medical stem cell services.

The role of the National Research Council and the National Bioethics Committee is pivotal to monitor and supervise the implementation of stem cells in teaching hospitals in Indonesia. These two agencies were formerly established by the Indonesian Government (the National Research Council on 7 January 1984 and The National Bioethics Committee on 17 September 2004).

2. The Indonesian Patent Act: An Overview

a) The Background of the Indonesian Patent Law

During the 1980s, the Indonesian government reviewed and restructured its intellectual property regulations. Starting with copyright law in 1982, legal reform was followed by the proposal of new patent bill in 1984. In 1989, the government formed a special team to prepare for the enactment of the Indonesian patent act.¹⁸ On September 12,

1989, the team began discussing the substance of the draft through special committees and working groups, wrapping up this process on October 9, 1989.¹⁹ In crafting the Patent Act, the government explained that it wanted to create a policy to reflect the important role of patents in improving research and technology in Indonesian development.²⁰

The government also considered that patent laws could attract foreigners to invest their capital in Indonesia and become instruments of technology transfer.²¹ It should also be acknowledged that another reason behind the creation of Indonesian intellectual property regulations in general (and patent law in particular) was international pressures from industrialized countries. This came in the form of economic pressure from Western countries, the USA in particular.²² Carlos Primo Braga states that the influence of economic dependency and the need for technology were the main reasons for strengthening intellectual property regulations in developing countries during the 1980s.²³

This argument seems plausible because during the 1980s, the Indonesian economy was heavily dependent on developed countries due to the decline in the oil price.²⁴ Because oil was one of Indonesia's main export commodities, this situation brought about a "difficult financial

¹⁸ Historically, the preparation of the draft was started at the beginning of the 1970's. Several activities, such as scientific meetings with experts from government, universities and private sectors to realize the draft were done by Badan Pembinaan Hukum Nasional (The National Legal Establishment Agency). This work succeeded in producing a patent draft in 1982 followed by the submission of this draft from the Minister of Justice to the President of the Republic of Indonesia at the same year. The revisions of the Indonesian Patent draft of 1982 were ongoing until 1986. Since 1986, the Tim Keppres 34, which was previously formed by the President, took over the task of making revisions of the draft by providing discussions with the industrial societies. A series of hearings with experts from other countries and the WIPO (World Intellectual Property Organization) were also held to compare the patent regulations from other nations. (the government's explanation on the Indonesian patent draft in front of the Indonesian Parliament Council on June 16, 1989 (in Iman Sjahputra Tunggal & Arif Djohan Tunggal, 1997, *Peraturan Perundang-undangan Hak Cipta, Paten dan Merek* (Laws and Regulations on Copyright, Patent and Trademark), Harvarindo, Jakarta. pp. 354-355.

¹⁹ The Welcoming Speech of the Minister of Justice for the approval of the Indonesian Patent Bill in front of the Indonesian Parliament Council, October 13, 1989; *Ibid.*, at 384-385.

²⁰ See the Indonesian Patent Act of 1989, Consideration a; see also the official patent draft explanation from the Minister of Justice in front of the members of the Indonesian parliament; *Ibid.*, at 358).

²¹ *Ibid.*, p. 358.

²² See Christoph Antons, "The Development of Intellectual Property Law in Indonesia: From Colonial To National Law", in Taylor V., 1997, *Asian Laws Through Australian Laws*, LBC International Services, Sidney.

²³ Carlos A. Primo Braga, "The Developing Country Case For and Against Intellectual Property Protection" in Paul Goldstein, 2001 *International Intellectual Property Law Cases And Materials*, Foundation Press, New Year, p. 67.

²⁴ Christoph Antons, *supra* note 22, at 375; see also Andrew MacIntyre, 1990, *Business And Politics In Indonesia*, Allen and Unwin., Sydney. p.3; see also Elizabeth Uphoff, 1991, *Intellectual Property and US Relations With Indonesia, Malaysia, Singapore, and Thailand*, South East Asia Program SEAP, New York, p. 34.

situation and the growing dependence on loans and foreign investment.²⁵ As a consequence, when developed countries demanded that the Indonesian government enact intellectual property regulations, including patent law, the government felt compelled to enact the regulations immediately. During the process of enacting the Indonesian patent act, the government tried to create a balance between patent holders' interests and the public interest. The Patent Act of 1989 provided exclusive rights to patent holders. The act also established procedures on how to defend those rights from unauthorized use or other patent infringements.²⁶

The government also protected public interests under Article 7 of the Indonesian Patent Act by excluding five areas from patent protection. These are:

- 1) Processes and products related to inventions that are contrary to existing laws, public order and morality;
- 2) Processes and products related to inventions for food and drink;
- 3) New plant varieties and animal species;
- 4) Inventions dealing with methods of examining, treatment, medication and / or surgery applied to humans and/or animals;
- 5) Any theory and method in the field of science and mathematics.

This policy aims to protect public interests in availability of basic necessities (food and drink) and the spread of science and knowledge to public.

The Indonesian government decided to revise its intellectual property regulations, including the Patent Act by the end of 1995²⁷, following the establishment of the World Trade Organization in 1994. In 1997, the Patent Act of 1989 was

amended - a condition of membership to the WTO was to comply with its international standards.²⁸

The 1997 Patent Law reflects Indonesia's commitment to the WTO's intellectual property or Trade Related Aspects of Intellectual Property Rights (TRIPS, agreement), despite its drawbacks. The Indonesian Patent Law of 1997 introduced important changes, such as extending the term of patent protection from 14 years to 20 years, changes to the scope of patentable subject matter and importation of patented products, and a compulsory license mechanism. Compliance is involuntary, based on the following reasons:

First, the extension of the duration of protection has little impact on Indonesian domestic development because domestic patent holders comprise only 3.15 percent of patent holders in Indonesia.²⁹ Since this provision only benefits foreigners rather than local patent holders, the 1997 Patent Law fulfills Indonesia's obligation to the TRIPS rather than helping Indonesian development.

Second, according to the TRIPS Agreement, Indonesia must comply with the TRIPS Agreement by the year 2000. However, the government enacted the 1997 Patent Law three years before the deadline. The motivation behind this policy was to align with Indonesian trade partners, primarily developed countries, which already had patent laws based upon the TRIPS Agreement since 1996.

Issues behind the 1997 Patent Law included the Indonesian economy's dependence on developed countries and the government's expectation that compliance with the TRIPS Agreement could help attract foreign capital investors for Indonesia.

²⁵ *Ibid.*

²⁶ The government explanation on the Indonesian Patent Draft in front of the Indonesian Parliament Council on June 16, 1989, *supra* note 19, pp. 360-361.

²⁷ In Christoph Antons, *et al.*, 1996, *Intellectual Property Harmonisation within ASEAN and APEC*, Kluwer Law International, p. 14.

²⁸ Insan Budi Maulana, 1999, *Kompilasi UU Hak Cipta, Paten, Merek dan Terjemahan Konvensi-Konvensi di Bidang Hak atas Kekayaan Intelektual (HaKI) Seri A* (Compilation of Copyright, Patent and Trademark Acts and the Translation of International Convention on Intellectual Property), PT Citra Aditya Bakti, Bandung, p. ix.

²⁹ Ansori Sinungan, 2002, "Kebijaksanaan Pemerintah Di Bidang Paten" (The Government's Policy On Patent), paper presented in the IPR Course under IASTP Project, June 2000 in Malang, at 7; see also Tim Lindsey *et al.*, *Hak Kekayaan Intelektual: Suatu Pengantar* (Intellectual Property Rights: An Introduction), PT Alumni, Bandung, p. 84.

Foreign investment could increase economic growth and national and international trade. The government expected trade barriers, raised because of insufficient protection of intellectual property protection, would be abolished.

In addition to these incentives for the Patent Act of 1997, a major factor was international pressure from the US government through its USTR (the United State Trade Representative) to revise the Indonesian Patent Act of 1989. Many developed countries, which were pharmaceutical producers, objected to Article 21 of the Indonesian Patent Act and Government Regulation No. 32 of 1991. They claimed the Indonesian government had failed to protect pharmaceutical products through the Indonesian Patent Act.³⁰

The US government was concerned with several features of the 1989 Act. These included the compulsory licenses provision, a relatively short term of patent protection and the policy of allowing the importation of 50 pharmaceutical products and materials from non-original producers.³¹

Although the 1997 Patent Law affected the cost and access for newer drugs in Indonesia, the government had no choice under the TRIPS Agreement. Each country that is a member of the WTO is obliged to provide sufficient protection for pharmaceutical inventions in their patent laws. The 1997 Patent Law came into force at the beginning of the year 2000. According to the 1998 NTE Report, the revision of the Indonesian Patent Act in 1997 improved patent protection. The US government, however, criticized the revised act for not fulfilling all the requirements of the TRIPS

Agreement, such as compulsory license and importation issues.³²

The US pharmaceutical industry, through the Pharmaceutical Research and Manufacturers of America (PhRMA) association, also responded to the revised Patent Act of 1997. According to the PhRMA, the revision was unsatisfactory because of the compulsory license issue, the importation of certain patented raw materials, patent cancellation concerns, counterfeit drugs from neighboring countries and generic drug prescriptions.³³

The economic crisis and fall of President Suharto in 1998, followed by the electoral process during President B.J Habibie's transition term in 1999 delayed revision of the Indonesian Patent Act. Due to this delay, weak intellectual property enforcement and a weak judicial system generally, the US government, based on a request from the PhRMA, put Indonesia on its watch country list.³⁴ In advocating for Indonesia to be placed on the watch country list, the PhRMA had noted the slow and confusing pharmaceutical product registration process under the Indonesian food and drugs administration (Dirjen POM), counterfeiting and drug smuggling, and generic prescribing.³⁵

In order to better comply with the TRIPS Agreement, the government amended patent law in 2001 to improve law enforcement. This occurred because in the post-TRIPS era, discussion about intellectual property evolved from theoretical compliance with the TRIPS Agreement to practical law enforcement of the Patent Act. Under Article 125 of the revised Patent Act of 2001³⁶, the introduction of injunctions

³⁰ See Insan Budi Maulana, 1996, *108 Tanya Jawab Paten, Merek dan Hak Cipta (108 Questions and Answers in Patent, Trademark and Copyright)*, Citra Aditya Bakti, Bandung, p. 25.

³¹ CP Tech (IP and Health), <http://www.cptech.org/ip/health/c/Indonesia>.

³² *Ibid.*

³³ *Ibid.*

³⁴ *Ibid.*

³⁵ *Ibid.*

³⁶ Through the Indonesian Patent Act of 2001, the government introduces several significant revisions as the reflection of the government's commitment to improve the protection of patent. These include: the revision of terminologies, new patentable subject matters, the empowerment of the commercial court and the improvement of dispute settlement system. In order to protect public interests the government also inserted Article 135 into the Patent Act. This provision permits *parallel importation* and *bolar provisions*, thereby attempting to provide cheap drugs to Indonesian citizens and maximizing the production of generic drugs.

in the Indonesian legal system constitutes a serious attempt from the Indonesian government to improve the patent law enforcement. It authorizes a party who might have suffered due to the implementation of a patent infringement? to request a provisional decision by the commercial court. It could issue an effective order to prevent the continuation of patent infringement, to keep the evidence dealing with the patent infringement and to request the party who might have suffered to provide evidence of such right being infringed. If the request is refused, a party who might have suffered by the request may file a claim to recover damages from the party who requested the decision (Article 128). This adoption reflects compliance with Part III of the TRIPS Agreement, which regulates the enforcement of intellectual property rights, particularly Article 41, Article 42 (fair and equitable procedures), Article 43 (evidence), Article 44 (injunctions), Article 45 (damages) and Article 46 (other remedies). According to the TRIPS Agreement and the Indonesian Patent Act of 2001, the application of injunctions occurs before the patent infringement is examined by the judges. This aims to prevent the continuation of patent infringement that might have damaged patent holders.

3. The Future of the Indonesian Stem Cell Patents Regulations and the Possibility of Adopting Stem Cell Patent Regulations and Policies in the USA, Germany and Korea.

Since the enactment of the first Indonesian patent law in 1989, there have been two important amendments made by the Indonesian Government, namely in 1997 and 2001. Among the 139 articles of the Indonesian Patent Act of 2001, Article 7 (unpatentable inventions) is the most relevant to the issue of patenting stem cells. Article 7 (a and d.i) of the Indonesian Patent Act stated that:

A patent shall not be granted to an invention regarding:

(a) any process or product for which the announcement and use or implementation contravenes prevailing rules and regulations, religions, religious morals, public order or ethics;[...]

(d.i) all living creatures, except micro-organisms.

In the general elucidation to the law, it is stated that the purpose of Article 7 is to accommodate public opinion, which calls for the invention of living organisms (plant, animal, and human) to not be patentable. What approaches should be chosen by the Indonesian Government as model to protect stem cell research under the Indonesian Patent Act and Non-Patent Regulations?

a) Patent Related Policies

In the 21st century, the international community has witnessed the rapid development of research and technology relating to living organisms. After the invention of Chakrabarty, research on living organisms became a significant priority of researchers. The focus of much discussion about living organisms has been whether microorganisms are patentable. The answer to this question is 'yes' in most jurisdictions. Although controversial, most countries in the world have permitted the patenting of microorganisms in their patent laws.

After animal cloning and embryonic stem cells were introduced to the public in the 1990s, the focus of discussion has changed: the question now is whether human embryonic stem cells should be patentable. The response of WTO members on this question varies – some allow it, but most prohibit it on moral and ethical grounds.

By August 2010, there were 74,757 patent applications in Indonesia, chiefly from foreign applicants (67,747 or 95%).³⁷ Some 25,499 patents of these were granted by the Indonesia IP office.³⁸ Based on 2002 data from LIPI (the Indonesian Institute of Sciences), most patent

³⁷ The Government's explanation on the Indonesian Patent Draft in front of the Indonesian Parliament Council on June 16, 1989 (Tunggal and Tunggal, *supra* note 26, at 367).

³⁸ Based on statistical data provided by the Indonesian IP Office (DGIP), <http://www.dgip.go.id>.

applications were in the field of chemistry and metallurgy, including products such as dyestuffs, fertilizers, fibers and pharmaceuticals (section c according to International Patent Classification or IPC system). These comprised about 26 percent of total patent applications.³⁹ Based on field research at The Directorate General of Intellectual Property Office, there have been no stem cell patents filed at the Directorate General of Intellectual Property in Indonesia by local scientists. The application of stem cells based inventions filed by foreign applicants is currently dominated by adult stem cells.⁴⁰

In order to define an appropriate model for developing stem cell research using a patent system in Indonesia, the following discussion will examine stem cell patents in three different countries, the USA, Germany and South Korea. These countries were chosen because they take different approaches to dealing with stem cell patents. Further, most stem cell patents are granted in the US and the EU follows. As of 2001, 727 patents from 2029 applications were granted in Europe and in the United States.⁴¹ Those stem cell patents include pluripotent embryonic stem cells, pluripotent embryonic germ cells, multipotent adult stem cells and multipotent foetal stem cells.⁴² South Korea was chosen because it is one of the leading countries in Asia in developing stem cell research. The country has also experienced a scandal regarding stem cell research, and has therefore been very careful in formulating its laws and policy on stem cells. It could thus provide an

alternative model to the US and EU that could be replicated in Indonesia.

1) Stem Cell Patents in the USA

The Cakrabarty decision was a key moment in the development of US Patent Law. In this case, the Supreme Court allowed the patenting of living organisms in the US. According to the court decision, a bacterium of the genus *Pseudomonas* was patentable under Section 101 of US Patent Law.⁴³ Following this decision, most countries have permitted the patenting of microorganisms. In April 1988, the USPTO issued a patent on the mouse known as “the Harvard Mouse.” This patent was very important because it was the first patent on multi-cellular living organism.⁴⁴ In 1993, a group of researchers in the United States successfully cloned seventeen human embryos and multiplied them into forty-eight embryos. This invention did not produce an entire organism.⁴⁵

The United States has responded rapidly to allow the patenting of human cloning. As mentioned, the Supreme Court allowed a bacterium to be patented for the first time in the Cakrabarty case. Similarly, the United States Patent and Trademark Office was the first IP office in the world to grant a patent for multi-cellular organism: “Onco Mouse”. Furthermore, the USA Patent System excludes moral and ethical issues to which opponents appeal when attacking patentability of animal and human cloning.⁴⁶

Consequently, the DNA and animal cloning patents granted by USPTO have prompted many

³⁹ Endang Sri Rusmiyati Rahayu & Zainal A Hasibuan, “Identification of Technology Trend on Indonesia Patent Documents and Research Reports on Chemistry and Metallurgy Fields”, in Christopher S.G. Khoo *et al.*, 2006, *Proceeding of the Asia-Pacific Conference on Library & Information Education & Practice 2006*, School of Communication & Information, Nanyang Technological University, Singapore, p. 582.

⁴⁰ Interview with Ahmad Muniri, a patent examiner at Directorate General of Intellectual Property Office, October 11, 2012.

⁴¹ Geertrui Van Overwalle, “Patentability of Human Stem Cells And Cell Lines”, in: Henrik Jorgensen & Anne Lykkeskov, 2005, *The Ethics of Patenting Human Genes and Stem Cells*, 2004, The Danish Council and Ethics, Copenhagen, p. 47.

⁴² *Ibid.*, p. 48.

⁴³ *Ibid.*, p. 7, see also William B. Hurlbut, 2005, *Patenting Humans: Clones, Chimeras, and Biological Artifacts*, 11 *Science and Engineering Ethics*, p. 21-22.

⁴⁴ *Ibid.*, p. 9; see also Graham Dutfield, 2009, *Intellectual Property Rights and the Life Science Industries – Past, Present and Future*, World Scientific Publishing Co. Pte. Ltd., Singapore, p. 199; see also William B. Hurlbut, *Op.cit.*, at 22.

⁴⁵ Craig M. Borowski, “Human Cloning Research in Japan: A Study in Science, Culture, Morality and Patent Law”, 9 *Indiana International and Comparative Law Review*, 505, 3, 1991, p. 9.

⁴⁶ Stacy J. Ratner, 1999, “BAA, BAA Cloned Sheep, Have You Any Law? Legislative Responses to Animal Cloning in the European Union and United States”, *Boston College International and Comparative Law Review*, 141, 5, 1991, p. 22.

scientists in the USA to apply for human embryonic stem cells. Geron Corp, a US company, received patents on certain types of human embryonic stem cell growth technology.⁴⁷ Since the “moral free” condition applies in patent applications in US, all types of technology are patentable as long as they fulfill the patent requirements under the US patent law.

2) Stem Cell Patents in Germany

Germany established a uniform patent system in 1877. However, under the patent act at that time, an inventor was not acknowledged as the sole legitimate proprietor. It was not until 1936 when inventors received this acknowledgement statute.⁴⁸ In order to simplify and modernize patent law, the German government amended its Patent Law on May 28, 2009. The revised patent law came into force on October 1, 2009.⁴⁹

Unlike the United States, the German government follows the policy in EU, where moral and ethical issues are important considerations affecting the granting of patents. This principle is regulated in Article 2, Paragraph 1, of the German Patent Act. The approach taken by most EU members has been heavily criticized by most European scientists arguing that it can act as a barrier to the advancement of science and technology in Europe.

Reasons for such concern can be seen in the German case of Oliver Bruestle, whose patents were challenged by Greenpeace. Bruestle is director of the Institute of Reconstructive Neurology at the University of Bonn and received a patent on stem cells in 1999. Greenpeace

filed a suit against Bruestle’s patent on the basis that the embryonic stem cell patent could lead to the development of an embryo industry.⁵⁰

The German Federal Patent Court ruled to partially reverse the 1999 patent, arguing that “anything culled from embryonic stem cells could not be patented, as it necessarily involved the destruction of human embryos.”⁵¹ Bruestle lodged an appeal, and the case could no longer be decided by the German Federal Court of Justice (BGH) in Karlsruhe. Rather, the European Court of Justice would rule on the case.⁵² The European Patent Office in Munich eventually rejected the 1999 patent granted to Bruestle on the grounds that “European patent law prohibits the patenting of human stem cell cultures whose preparation necessarily involves the destruction of human embryos.”⁵³ The EPO’s decision to reject Bruestle’s patent mirrored a similar case in 1995, when the office ruled against a patent application for the use of embryonic stem cells by the Wisconsin Alumni Research Foundation.⁵⁴

The EPO’s decisions on stem cell patents have no effect on the legality of doing stem cell research in German or in other EU members. It is clear, however, that embryonic stem cell research is unpatentable under the German Patent Law.⁵⁵ This will undeniably discourage scientists and companies from conducting more research on stem cells for commercial purposes.⁵⁶ Responding to the EPO decision, Bruestle commented that he hoped embryonic stem cell patents could be recognized because of the important incentive patents provide for scientists and companies to

⁴⁷ DW-World, “Europe Rejects Patent on Embryonic Stem Cells”, http://www.dw-world.de/popups/popup_printcontent/0,,3828268,00.html, retrieved on 10 September 2010.

⁴⁸ Peter Ruess, “Accepting Exceptions?: A Comparative Approach to Experimental Use in U.S. and German Patent Law”, *Marquette Intellectual Property Law Review*, 83, 2006, p. 10.

⁴⁹ Christoph De Coster, “German Parliament Adopts Amended Patent Law Bill”, http://www.taylorwessing.com/Uploads/tx_Siruplawyermanagement/DAS_Christoph_de_Coster_english_01.pdf; retrieved on 12 September 2010.

⁵⁰ DW-World, “Patents are Crucial to Embryonic Stem Cell Research”, http://www.dw-world.de/popups/popup_printcontent/0,,4898622,00.html, retrieved on 10 September 2010.

⁵¹ DW-World, “Europe to Decide Over Patenting of Human Embryo Research”, http://www.dw-world.de/popups/popup_printcontent/0,,4884212,00.html, retrieved on 10 September 2010.

⁵² *Ibid.*, at 1.

⁵³ DW-World, “Europe Rejects Patent on Embryonic Stem Cells”, *supra* note 42, at 1.

⁵⁴ *Ibid.*, at 1.

⁵⁵ DW-World, “Europe to Decide Over Patenting of Human Embryo Research”, *supra* note 46, at 1.

⁵⁶ DW-World, “Europe Rejects Patent on Embryonic Stem Cells”, *supra* note 48, at 1.

conduct stem cell research.⁵⁷

3) Stem Cell Patents in South Korea

The Korean government instituted its first national patent system in 1961.⁵⁸ One of the weaknesses of the patent Act of 1961 was that it did not protect product and process patents for food, chemical products and pharmaceuticals.⁵⁹ In 1981, the Patent Act of 1961 was amended to include several important issues, such as weakening the provisions on patent revocation for nonworking of a patent, allowing single applications for multiple claims, allowing foreign nationals to apply for patents and regulating non-patentable subject matter.⁶⁰ In 1986, the Korean government again amended its patent act by changing the provisions on patentable subject matter. Under this new law, chemical and pharmaceutical products could be patented.⁶¹ The Patent Act was then amended on January 13, 1990, and was followed by a series of revisions between 1993 and 2005.⁶² In 2007, the government again amended several provisions in the act. The significant changes made included the introduction of grace period, reduced description of requirement, ways to draft claims, notice of rejection, opportunity to file a petition for correction, abandoning the benefit of deadline and refund of official fees.⁶³

Stem cells can now be patented in Korea, provided the application fulfills Article 29 and Article 32 of the Korean Patent Act (requirements for patents and unpatentable inventions respectively). Patents will not be granted to

inventions that contravene public order, morality or injure public health.

From the discussion of the US, Germany and Korean patent laws dealing with the patentability of stem cell research, I conclude that the three countries are responsive and accommodative to recent developments and the situation in their respective countries. All governments attempt to ensure patent law provides benefits for the country and its citizens.

Aside from this superficial similarity, however, the philosophy behind the protection of patents in the three countries is completely different. The US emphasizes establishing strong domestic stem cell companies through several comprehensive policies, such as moral-free provisions on patent examination procedures and applications under its patent law, and transfer of technology under the Bayh-Dohle Act. This policy is derived from the US government's commitment to ensuring the patent law is an effective tool to develop science and technology as regulated in the US Constitution. This approach has led to most stem cell products being patented in the US, with the majority consisting of embryonic stem cells. One such example is the three patents of human embryonic stem cells (HESC) owned by the Wisconsin Alumni Research Foundation (WARF),⁶⁴ which were patented in 1995, 1998 and 2001.⁶⁵ The patents were not free of controversy, however. At one point they were threatened with cancellation by the Public Patent Foundation in New York and the Foundation for Taxpayer and

⁵⁷ DW-World, "Patents are Crucial to Embryonic Stem Cell Research", *supra* note 45, at 1.

⁵⁸ Sumner J. LaCroix & Akihiko Kawaura, "Product Patent Reform and Its Impact on Korea's Pharmaceutical Industry", *International Economic Journal*, 111, 1996, p. 10; see also Nagesh Kumar, "Study Paper 1b Intellectual Property Rights, Technology and Economic Development: Experiences of Asian Countries", http://www.iprcommission.org/papers/pdfs/study_papers/sp1b_Kumar_Study.pdf, retrieved on 11 September 2010.

⁵⁹ Nagesh Kumar, *Ibid.*, p. 5.

⁶⁰ La Croix & Kawaura, *Op.cit.*, p. 112.

⁶¹ *Ibid.*

⁶² Wikisource, "Patent Act of South Korea", http://en.wikisource.org/wiki/Patent_Act_of_South_Korea, retrieved on 11 September 2010.

⁶³ Yoon-Seong Cho & Kevin Lee, "Recent Changes in the Patent Act", <http://www.ip.kimchang.com/UserFiles/files/World%20IP%20Contacts%20Handbook%202007.Korea.YSC,KKL.pdf>, retrieved on 11 September 2010.

⁶⁴ Warren D. Woessner, "The Evolution of Patents on Life-Transgenic Animals, Clones and Stem Cells", *Journal of Patent and Trademark Office Society*, 840, 2001, p. 83, see also Russel Korobkin & Stephen R. Munzer, 2007, *Stem Cell Century-Law and Policy for a Breakthrough Technology*, New Haven, USA, p. 93

⁶⁵ USA Today, "Two Stem Cell Patents Upheld for Wis. Research", <http://www.usatoday.com/clearprint/?1285362655640>, retrieved on 24 September 2010.

Consumer Rights (FTCR) in Los Angeles on the grounds that they “impede stem cell research, and that other researchers before Thomson had developed the technology.”⁶⁶ In March 2008, the US Patent Trademark Office (USPTO) decided to uphold two of the three patents (the second and the third patents) owned by WARF.⁶⁷

Meanwhile, patent procedures in Germany are dominated by human rights principles and are influenced by the power of nongovernmental organizations. European and German history has also played a role in hampering German efforts to legalize stem cell patents. Not surprisingly, when nongovernmental organizations or members of the public file suits against granted patents on the grounds of moral or human rights issues, decisions tend to go in the NGO or public’s favor. This was clearly the case in the European Patent Office’s 2008 decision to reject the 1999 patent granted to Bruestle, on the grounds that it involved the destruction of human embryos. Parallel to this case was the EPO’s decision to reject the three patent applications on human embryonic stem cells (hESC) made by WARF at the end of 2008. The office objected to the use of human embryos and claimed that such use was against morality.⁶⁸ The EPO decision on WARF’s patents reflects the different approach and basic philosophical considerations with the USPTO.

The South Korean government, meanwhile, treads a safer path when dealing with stem cell patents. The section defining products subject to non-patentability reflects the dynamic response to the changes occurring with the rapid pace of development in science and technology, including embryonic stem cell research. In South Korea, for an invention to be patentable, it must “not conflict with moral and public order.” The Korean

patent law is thus flexible and does not need to be amended frequently. Further, the provision runs parallel to the special Korean Act on Bioethics and Safety, which highly supports research on human adult stem cells. Research on adult stem cells does not destroy embryos during the process of obtaining stem cells. Stem cell products derived from this type of research thus fall into patentability categories, as long as they fulfill other patent requirements, such as novelty, the use of inventive steps and usefulness or applicability to industry.

Reflecting on these various approaches, the US experience seems least applicable for Indonesian stem cell research development. In addition, the moral-free patent policy could create social problems in Indonesia. Meanwhile, the German and Korean approaches are more acceptable because the considerations for granting patents are mainly based on moral issues. These approaches could therefore be considered models for Indonesia. Using the South Korean and German approaches as a guide, there are still several issues that must be resolved regarding the protection of stem cell research under the Indonesia Patent Law.

- (a) As in Germany and South Korea, the government should maintain or keep the substance of Article 7 and its elucidation, where patent examination is based on moral issues. Agus Purwadianto, a chairman of Ethics Reviewer Board of IDI (Indonesian Medical Association) and Ahmad Muniri, a patent examiner at the Directorate General of Intellectual Property also agree with this opinion. They said that Article 7 of the Indonesian Patent Act can be used as a filter or main

⁶⁶ The Scientist, “Europe Rejects Stem Cell Patent”, <http://www.the-scientist.com/blog/display/55249>, retrieved on 24 September 2010.

⁶⁷ Science Progress, “EU Rejects Stem Cell Patent Applications”, <http://www.scienceprogress.org/2008/12/eu-rejects-stem-cell-patent-applications/print/>, retrieved on 24 September 2010.

⁶⁸ Lori P. Knowles, “Stem Cell Patents, Stem Cell Network”, <http://www.stemcellnetwork.ca/uploads/File/Whitepapers/Stem-Cell-Patents.pdf>, retrieved on 24 September 2010. Dealing with patenting of human genes and living organisms, Straus emphasized on the role of national court to “decide what is contrary to morality and public order in their countries”, see Joseph Straus, “Patenting of Human Genes and Living Organisms”, in Friedrich Vogel & Reinhard Grunwald, 1994, *Patenting of Human Genes and Living Organisms*, Springer-Verlag, Berlin, p. 25.

indicators in determining whether stem cells related inventions are patentable under the Indonesian Patent Act.⁶⁹ Such a provision is relevant to the conditions in Indonesia and the current status of stem cell research in the country. As noted in the South Korean case, only human adult stem cells do not contravene moral considerations.⁷⁰ This means that under Article 7, only human adult stem cells are patentable in Indonesia.

- (b) Even though human adult stem cells are the type of stem cells supported by the government, the next amendment of the Indonesian Patent Act should not mention human adult stem cells explicitly in Article 7 or in its elucidation. This is also in line with patent policies in Germany and South Korea. Technology and science, including stem cell research, develop rapidly. By not mentioning human adult stem cells specifically, future amendment of the patent act could be avoided.
- (c) The Indonesian government should provide specific guidelines to patent examiners regarding how to conduct patent examination on stem cell-related patent applications. These guidelines can prevent abuse of stem cell patents by restricting activities to administrative procedures.

b) Non-Patent or National Laws Approach

From the perspectives of non-patent or national laws, stem cell research in Indonesia is regulated under three regulations: the Law on Health, the Minister of Health Regulation and the Ministry of Health Decree on the Guidelines of using stem cells. In the three regulations on stem cells, it is regulated the functions of related agencies dealing with the implementation of stem cells for health services in Indonesia. The Ministry

of Health is responsible for monitoring research and the use of stem cells in teaching hospitals. Meanwhile the National Research Council and the National Bioethics Committee are responsible to monitor the practice of stem cell storage in banks outside hospitals.

Regarding the implication of stem cells as drugs, there is another institution which is responsible for managing stem cell research; Badan POM or National Agency of Drug and Food Control (NA-FDC). This institution manages stem cell research dealing with drugs (biological drugs) under blood products classifications.⁷¹

Even though the responsibilities of these agencies are regulated in those regulations, they do not cover the issues dealing with multi-disciplinary character of stem cell implementation which involve more than two agencies. Which institutions should be involved in reviewing the application of stem cell research in Indonesia? For example, should this function be located in the Ministry of Research and technology, the Ministry of Health, or should it be expanded into a special coalition consisting of these institutions and others, such as the Department of Health and Directorate General of Intellectual Property and NA-FDC? Unlike Indonesia, other developed countries (such as USA) have a single institution to manage stem cell research, namely Food and Drug Administration (FDA). In the future, the Indonesian government should take multidisciplinary approach in regulating stem cells under non-patent regulations.

4. The Types of Stem Cells Should be Protected by the Indonesian Patent Act

As discussed earlier, there are two types of stem cells: embryonic stem cells and non-embryonic stem cells (adult stem cells). According to experts that I interview during field research, compared to embryonic stem cells, non-embryonic stem cells

⁶⁹ Interview with Agus Purwadianto was held on October 6, 2012. Meanwhile interview with Achmad Muniri was held on October 11, 2012.

⁷⁰ See Deryck Beyleveld & Roger Brownsword, 2001, *Human Dignity in Bioethics and Biolaw*, Oxford University Press, New York, p. 224-225.

⁷¹ Interviews with Jimmy Susanto, principal investigator, Stem Cell and Cancer Institute Jakarta on October 6, 2012 and a staff NA-DFC on October 6, 2012.

or adult stem cells are suitable for conditions in Indonesia and would be acceptable from a moral and religious perspective.⁷² Therefore, the types of stem cells which are eligible as patentable subject matters should be adult stem cells. This opinion seems consistent with the provisions in three regulations which regulate stem cells in Indonesia, namely: the Law on Health, the Minister of Health Regulation and the Ministry of Health Decree on the Guidelines of using stem cells. Through these regulations, the government has defined the type of stem cells appropriate for use in health services as non-embryonic stem cells only. Non-embryonic stem cells are mentioned in a provision, and the types of stem cells for the next provisions are described simply as stem cells.

The use of non-embryonic stem cells (adult stem cells) in Indonesia could address a great need, since the majority of the Indonesian people have limited access to essential medicines for particular diseases. Infectious diseases, such as tuberculosis and malaria are major causes of death in Indonesia, while non-infectious conditions such as cardiovascular and chronic diseases are increasing, particularly in urban areas. HIV/AIDS infection is also increasing.⁷³ Due to life-style changes, many Indonesians now suffer non-infectious diseases, such as stroke, heart disease, cancer, metabolic disorders, and circulatory diseases.⁷⁴ In 2000, stroke, heart disease and diabetes were among the top seven non-communicable diseases causing the highest death in Indonesia.⁷⁵ In 2001, 2,593 HIV cases and 671 AIDS cases were reported in Indonesia, and it was estimated that there were 80,000 to 120,000 were infected with HIV.⁷⁶ Even though

stem cells could be more expensive and limited, the existence and the benefits of stem cells bring new hope to Indonesians.

D. Conclusions

Since the number of degenerative diseases is significantly growing in Indonesia, the government should support human adult stem cell research by improving the contents of *sui generis* regulations on stem cells. A set of proposed strategies, such as training of health professionals, use of patient care guidelines and government financing of adult stem cell research should be prioritized by the government to ensure research is sustainable.

This article also describes the difficulties faced by the Indonesian government during the process of patent enactment in Indonesia. It has described the policy revisions undertaken prior to adopting the TRIPS Agreement. These changes reflect the government's sensitivity to the TRIPS Agreement. In order to optimize the benefits of stem cells, the Indonesian Patent Act should not mention stem cells explicitly. Using this approach, it is hoped that human adult stem cell research can be developed further and encourage scientists to do more research in this area.

The current and future development of stem cell research in Indonesia is complex and affects a variety of stakeholders. It deserves a multidisciplinary analysis and solution. A national health needs assessment might initially focus on adult stem cell research and treatment priorities for common conditions in Indonesia as determined by an expert multidisciplinary panel. Their findings will help to guide planning and coordination of efforts across sectors.

⁷² Interviews with Agus Purwadianto on October 6, 2012 and Jimmy Susanto, a principal investigator, Stem Cell and Cancer Institute, Jakarta on October 6, 2012; see also Pusat Riset Biomedik (CEBIOR) FK UNDIP, "Harapan Baru Pengobatan Sel Punca di Indonesia" (A New Hope on the stem Cell Therapy), <http://www.id.cebior.co.cc/index.php?option=comcontent&task=view&id=22&Itemid=1>, retrieved on 06 September 2010.

⁷³ WHO, "Macroeconomics and Health – Indonesia Country Profile", at 3, http://www.who.int/macrohealth/action/en/rep04_indonesia.pdf, retrieved on 03 June 2006; see also ADB, "Supporting Health Systems in Indonesia", CGI Health Working Group Meeting, 10 December 2003, Jakarta, p. 1, [http://Inweb18Worldbank.org/eap/eap.nsf/Attachments/CGI-1203-ADB-health/\\$File/ADB-Health.pdf](http://Inweb18Worldbank.org/eap/eap.nsf/Attachments/CGI-1203-ADB-health/$File/ADB-Health.pdf), retrieved on 03 June 2006; Depkes RI (The Ministry of Health), *supra* note 7, p. 37-39, 48.

⁷⁴ The Indian Embassy in Jakarta, *supra* note 7, p. 77-78.

⁷⁵ *Ibid.*, p. 78; see also Depkes RI (The Ministry of Health), *supra* note 73, p.48.

⁷⁶ Depkes RI (The Ministry of Health); *Ibid.*, p. 39-40.

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