Fostering Innovation and Affordability: An Empirical Study Delving into Intellectual Property Protection of Human Stem Cell Based Invention/Innovation

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Abstract

The research article is based on the quantitative analysis of six (6) questions from the thirteen (13) questions comprising the questionnaire used in the doctoral study of the first author. The survey was conducted over a span of five months and 31 respondents from 16 different countries participated in the study. The survey questionnaire being a "mixed-type' was analyzed both quantitatively and qualitatively. This article is the publication of the quantitative analysis of those six (6) questions that deal with the intellectual property protection of human Stem Cell based Inventions/ Innovations (hSCI). The study investigated the appropriateness of the patent system for hSCI. The respondents having diverse background on Intellectual Property Right (IPR), bioethics and life science made substantial contribution in understanding the future IPR protection for hSCI. However, due to constraint in sample size, very few results from the logistic regression relationship analysis of different variables were statistically significant. While the existing patent system was favored by the legal professionals for the protection of hSCI, the respondents from the countries of high income economy are interested to see a new legal framework for inventions that uses the biological material of human origin and targeted to heath care. The elderly age group (51-65 years) did not support the proprietary nature of the IPR for hSCI. As the patent system works more territorially, than internationally, developing a new international legal framework for the intellectual property protection of hSCI or inventions that use the biological

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material of human origin is also a challenging task, considering the prevailing differences of opinion on ethical issues among the countries. There can be some changes in the patent system to pave the way for wider access to the therapy, but the idea of developing a new legal framework for those inventions targeted to health care found support to serve that purpose as well.

Keywords: Stem cell, invention, innovation, patent

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I. Introduction

The patent system is multilayered comprising of the international, regional and national legal framework. It also differs amongst countries in substantive interpretation of the patentability and exclusion from the patentability.[1] Samantha A. Jameson comments, "[i]n the U.S., patent law is not considered an appropriate place to exercise moral judgments about science."[2] But in Europe, an invention can be excluded from patenting on the grounds of *ordre public* or morality.[3]

Diamond v. Chakrabarty[4] commenced the era of patenting the living things. It is the first case where the United States Supreme Court declared

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[1] Patenting inventions derived from human embryonic stem cell lines is possible in the U.S.A. Some of those U.S. patents on hESC related inventions include United States Patent No. 8,785,185, issued on July 22, 2014, assigned to Janssen Biotech, Inc. (Horsham, PA) and The Cleveland Clinic Foundation (Cleveland, OH) by the inventors Jean Xu and Jan Jensen; United States Patent No. 8,742,200, issued on June 3, 2014, assigned to Advanced Cell Technology, Inc. (Marlborough, MA) by the inventors Young Gie Chung, Robert Lanza and Irina V. Klimanskaya; United States Patent No. 8,710,190, issued on April 29, 2014, assigned to Agency for Science, Technology and Research (Singapore, SG) by the inventors Andre Choo and Steve Oh. *See* United States Patent and Trademark Office, *USPTO Patent Full-Text and Image Database*, *available at* http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO2&Sect2=HITOFF&p=3&u=%2Fnetahtml%2FPTO%2Fsearch-bool.html&r=0&f=S&l=50&co1=AND&d=PTXT&s1=%22human+embryonic%22&s2=%22stem+cell%22&Page=Next&OS=%22human+embryonic%22+AND+%22stem+cell%22&RS=%22human+embryonic%22+AND+%22stem+cell%22 (last visited July 28, 2014).

On the contrary, a wide ban exists on patenting the inventions that destroys the human embryo in Europe. The judgment of CJEU in the case of *Oliver Brüstle* (2011) interpreted the relevant provisions of the Biotech Directive (1998) in a very strict way and the decision will curtail the hESC research freedom to a great extent, as it limits the patentability of inventions encompassing the destruction of human embryo. *Oliver Brüstle v. Greenpeace e.V*, C-34/10, Judgment of the Court (Grand Chamber) 18 Oct. 2011, *available at* http://curia.europa.eu/juris/liste.jsf?language=en&num=C-34/10 (last visited July 25, 2014). According to Article 6 of the Biotech Directive, "uses of human embryos for industrial or commercial purposes" shall entail an invention "unpatentable", on the grounds of "ordre public or morality." Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions, O.J.L.213, P. 0013-0021, (30/07/1998).

[2] Samantha A. Jameson, *A Comparison of the Patentability and Patent Scope of Biotechnological Inventions in The United States and the European Union*, 35 AIPLA Q.J. 193, 202 (2007).

[3] According to the Article 53 (a) of the European Patent Convention, "inventions the commercial exploitation of which would be contrary to 'ordre public' or 'morality' are excluded from patenting." European Patent Convention, Oct. 5, 1973, a*vailable at* http://www.epo.org/law-practice/legal-texts/html/epc/2013/e/ar53.html.

[4] 447 U.S. 303 (1980).

that the microorganisms and its process are patentable inventions under the section 101[5] of the U.S. Code.[6] In the United States, the inclusion of microorganism as patentable invention happened in 1980 (by the decision of *Diamond v. Chakrabarty*), several decades after the plant patent for the asexually reproduced plants were made available in 1930 (through the Plant Patent Act, 1930).[7] Although the newer kinds of inventions/innovations were included under the umbrella of patent successively in the technologically advanced word, the question appears that how appropriate it is to offer patent for such inventions that require the reconstruction of the perceptional and definitional boundary of the "invention" itself and its patentability. Human Stem Cell based Inventions/Innovations (hereinafter referred to as hSCI) having its distinct and evolving approach of reinventing itself as a science, makes it a perfect topic to conduct an investigative empirical study on its patenting. For the purpose of this research, the hSCI shall mean those creations that originate from all kinds of the human stem cell researches. The human stem cell researches, at present, showing promising progress in hESC (human Embryonic Stem Cell), SCNT (Somatic Cell Nuclear Transfer) and iPSC (induced Pluripotent Stem Cell) technologies. The hESC based inventions/innovations face a substantial barrier in patenting in some jurisdictions for the exclusion on "ethical" grounds, due to embryo destruction for the derivation of the stem cells. Since patent is apparently the most lucrative and feasible tool for the recovery of investment in research and development available to the inventors and sponsors, its appropriateness and contribution in offering the "*incentive for innovation*" and making the therapies *accessible* in affordable means is tested through this empirical research.

The empirical study and the subsequent data analyses conducted, both qualitative[8] and quantitative, are limited by the small number of participating respondents. As it is extremely difficult to have responses from a sufficiently large number of randomly chosen experts from such diverse backgrounds related to Intellectual Property Right ("IPR"), bioethics and life sciences, adopting a convenience sampling approach was the most rational and feasible choice. Accordingly, 31 respondents representing 16 different countries across the globe[9] took part in the study. The sample size despite

[5] 35 U.S.C. § 101 states that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title." 35 U.S.C § 101 (2011).

[6] *See* Diamond v. Chakrabarty 447 U.S. 303 (1980).

[7] At present, 35 U.S.C. § 161 provides the provision for plant patent in the U.S.A.

[8] The qualitative analysis conducted for the study is not included in this paper.

[9] The countries are from the continents of Africa, Americas, Asia, and Europe.

being relatively small is acceptable from the statistical point of view. Although the numerical summary provided a good overview of the response pattern, through tabular and graphical representations, it does not necessarily indicate association between two variables involved in the study questions to be statistically significant. As most of the variables were categorical in nature, properly coding them into dummy variables with binary values and employing logistic regression analyses to check for possible association seemed most appropriate. Due to the sample size constraints, relatively few numbers of associations turned out to be statistically "significant" at an alpha level of 0.05 while many results did show "promising trends." Nevertheless, the significant results and the positive trends observed using this small number of respondents are definitely intriguing and deserve due consideration. From a qualitative standpoint, the respondents were quite diverse in their opinion and many chose to express in their own words rather than selecting the suggested options that were provided in the questionnaire. This publication represents the quantitative analysis of the 6 questions from the 13 questions in the questionnaire of the study.

The article is comprised of five chapters. Chapter I give a brief introduction. Chapter II elaborates the empirical study design which includes the key questions explored through the study, the participating respondents and their demographic features, an overall sketch of the sequential steps in the data analysis and the primary objectives for performing this analysis. Chapter III presents an instrumental structure of the data analysis methodology involved. It incorporates the survey numerical summary and the predictor-response variable relationships being tested in tabular forms. The software code translations of STATA SE 13 related to binary and continuous variables are provided in the footnotes of this chapter. The key findings from the numerical summary and logistic regression analysis are incorporated in Chapter IV. An overall interpretation of the "significant" findings from the regression analysis conducted through the software is also eloquently presented in this chapter. Due to the limitation of characters, the complete "Logistic Regression Analysis Table" and the "STATA Software Output" are not published in this writing. Finally, Chapter V presents a brief conclusion by the way of recommendation.

II. Empirical Study Design

The study took place between September 2013 and January 2014. The study was conducted to see the appropriateness of the patent system for the hSCI and to explore the best possible way to protect those innovations that would create the environment for wider accessibility of the therapy in one hand and allow adequate incentive for the invention/ innovation on the other hand. How the experts/professionals suggest and view the current

circumstances and what they see as areas deserving attention in future was investigated through a partly structured, partly open-ended questionnaire. It was a difficult task to find and reach to the appropriate respondents, as the respondents for the study were needed to be experts or professionals in one or more fields connected to the bioethics, intellectual property law and life science.[10] The study was conducted by sending the questionnaire template by email to the expert respondents and the answers were also received by email correspondence. The respondents were free to choose from the suggested options and also write their own answers or comments as they deem fit. Age group, gender, country (with respective Gross National Income) and profession are the demographic independent/predictor variables for the purpose of the data analysis. Names of the respondents were optional and for the purpose of the statistical analysis, it has not been taken into account.

The empirical study and the subsequent data analyses conducted and presented in this writing comprise of the following sequential steps shown in Figure 1.

[10] The interdisciplinary nature of the study made it a challenging endeavor to find the appropriate respondents.

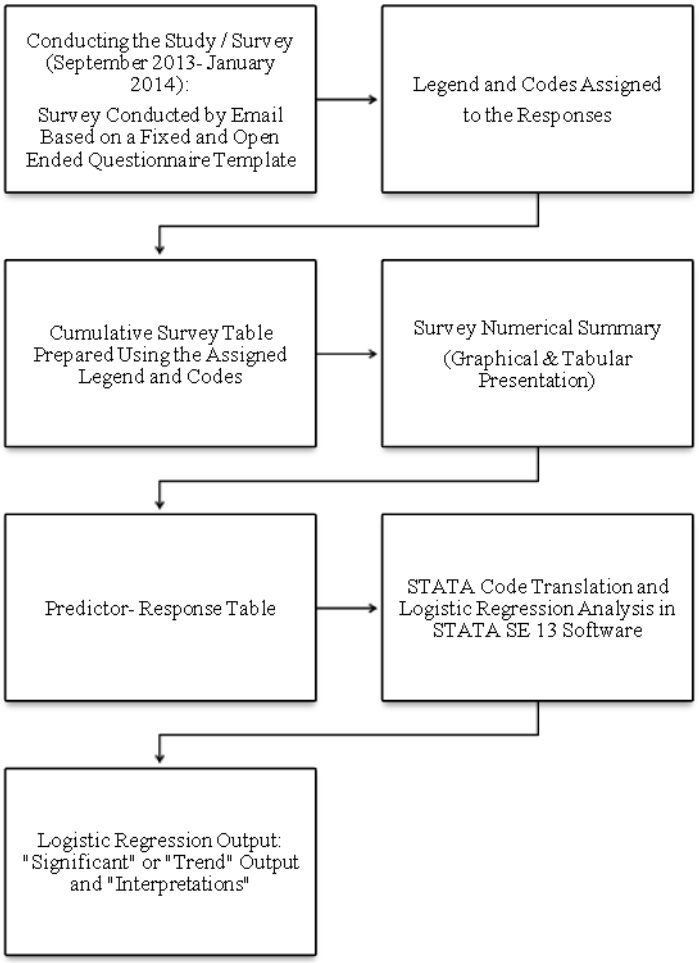

Figure 1: Research and Quantitative Data Analysis: Sequence of Actions

A. Survey Questions and the Expert Respondents

Considering the diverse approach the respondents might have due to their different fields of expertise, country backgrounds and personal experience, the questions in the questionnaire are designed from a more general approach, rather than making it too specific to certain context. Only 6 questions from the total of 13 questions of the questionnaire are chosen for this article. The questions chosen for this writing are the following:

Question 6[11]: Do you think patent protection as it exists today is the best way to provide incentive to human stem cell inventions/ innovations?[12]

[11] As it was numbered in the questionnaire.

[12] The responses with the codes for the data analysis are the following:

• Yes = coded as 0

• No = coded as 1

Question 7: Do you think that a new protection mechanism/ framework can be/ should be developed within the purview of intellectual property law (IPR), separate from patent, for the inventions/ innovations that use biological materials of human origin and targeted to health care?[13]

Question 8: How many years of protection (term of protection for commercial exploitation) is appropriate for human stem cell inventions/ innovations?[14]

Question 10: Who, according to your opinion, should be entitled to the intellectual property rights (IPR) of human stem cell inventions/ innovations?[15]

• No, because patent has embarked into too much complications and uncertainty of enforcement = coded as 2

• No, because it is inappropriate for rewarding inventions/innovations in life science = coded as 3

• No, because patented inventions are property of the patentee/assignee and it invokes exclusive commercialization = coded as 4

• No, because patented human stem cell invention/innovation is a form of commercialization of 'life' = coded as 5

• Other responses/ opinions = coded as 6

• 3+5 = coded as 7

• 3+ 6 = coded as 8

• 4+5 = coded as 9

• 2+3+4 = coded as 10

[13] The responses with the codes for the data analysis are the following:

• Yes (can be) = coded as 1

• Yes (should be) = coded as 2

• No = coded as 0

• Other opinion = coded as 3

• 0 + 3 = coded as 4

[14] The responses with the codes for the data analysis are the following:

• More than 20 years = coded as 1

• 20 years = coded as 2

• 15 years = coded as 3

• 10 years = coded as 4

• 5 years = coded as 5

• No protection = coded as 0

• 1+ 2= coded as 6

[15] The responses with the codes for the data analysis are the following:

• Scientist/ Inventor = coded as 1

• Employer organization/ University/ Assignee = coded as 2

• Both Scientist/ Inventor and Employer organization/ University/ Assignee = coded as 3

• State through its Department responsible for heath care = coded as 4

• None of the above /other opinion = coded as 5 (Note: In other opinion some experts have mentioned some of the entity mentioned above jointly with their prescribed entity)

• No one should own IPR of human stem cell inventions/ innovations = coded as 0

Question 12: Do you think legal obligation for issuing "licenses on easy terms" or "compulsory licenses" and "technology transfer" can bring benefit to the patients by ensuring availability of medication/treatment at a reduced cost and may also serve as incentive for the IPR right owner of human stem cell inventions/innovations at the same time?[16]

Question 13: Do you think public opinion should be sought and be given importance after the invention/ innovation is put to the market for commercial exploitation, in order to measure the impacts of the IPR protected invention/ innovation on the health care receiver?[17]

The following tables from the survey numerical summary show from which countries the respondents are taking apart. From the perspective of Gross National Income ("GNI") per capita, the participation appears as follows:

Table 1

Country	Frequency	Percent	Cumulative %
Bangladesh	1	3.23	3.23
Botswana	1	3.23	6.45
Chile	1	3.23	9.68
India	1	3.23	12.9
Denmark	1	3.23	16.13
Egypt	2	6.45	22.58

• 1+ 5 = coded as 6
• 3+ 4 = coded as 7

[16] The responses with the codes for the data analysis are the following:
• Yes = coded as 1
• Yes, but for the cost reduction the public health care sector has to be involved = coded as 2
• Yes, cost reduction is possible if the licenses are issued in favor of local pharmaceutical companies/ hospitals and therapies and medications are manufactured and produced locally = coded as 3
• I think yes but I am not so sure = coded as 4
• No = coded as 0
• Other opinion = coded as 5
• 0+5 = coded as 6
• 2+3 = coded as 7

[17] The responses with the codes for the data analysis are the following:
• Yes= coded as 1
• Yes, and public opinion can be received online= coded as 2
• No= coded as 0
• Specific opinion/ suggestion about seeking public opinion = coded as 3
• 0+3 = coded as 4
• 1+2 = coded as 5

Kyrgyzstan	1	3.23	25.81
Malaysia	1	3.23	29.03
Italy	5	16.13	45.16
Japan	1	3.23	48.39
Lithuania	8	25.81	74.19
Spain	1	3.23	77.42
Suriname	1	3.23	80.65
UAE	1	3.23	83.87
USA	4	12.9	96.77
Mexico	1	3.23	100
Total	**31**	**100**	

Table 2

Country	**Gross National Income (GNI) per capita in US$**[18]	**Frequency**	**Percent**	**Cumulative %**
Bangladesh	840	1	3.23	3.23
Kyrgyzstan	990	1	3.23	6.45
India	1580	1	3.23	9.68
Egypt	2980	2	6.45	16.13
Botswana	7650	1	3.23	19.35
Suriname	8680	1	3.23	22.58
Mexico	9640	1	3.23	25.81
Malaysia	9820	1	3.23	29.03
Lithuania	13830	8	25.81	54.84
Chile	14310	1	3.23	58.06
Spain	29620	1	3.23	61.29
Italy	33860	5	16.13	77.42
UAE	35770	1	3.23	80.65
Japan	47880	1	3.23	83.87
U.S.A.	52340	4	12.9	96.77
Denmark	59850	1	3.23	100

[18] *See* World Bank, *GNI Per Capita, Atlas Method (Current US$)*, http://data.worldbank.org/indicator/NY.GNP.PCAP.CD/countries (last visited Mar. 4, 2014) (update frequency of GNI per capita data is quarterly and the referred one represents 4th quarterly update in December, 2013).

Total		**31**	**100**	

Following the World Bank Classification of Countries[19] based on GNI per capita, the respondents can be grouped as follows:

Table 3

Country Economy Group	Frequency	Percent	Cumulative %
High	22	70.97	70.97
Low	2	6.45	77.42
Lower middle	3	9.68	87.1
Upper middle	4	12.9	100
Total	**31**	**100**	

The respondents have the expertise in the respective "profession" mentioned in the table below[20]:

Table 4

Profession	Frequency	Percent	Cumulative %
Academic	2	6.45	6.45
Ethicist/Bioethicist	2	6.45	12.9
Lawyer	5	16.13	29.03
Patent Examiner	2	6.45	35.48
Patient Advocate	2	6.45	41.94
Physician	1	3.23	45.16
Researcher	2	6.45	51.61
Academic & Lawyer	3	9.68	61.29
Academic & Researcher	3	9.68	70.97
Academic, Bioethicist & Physician	1	3.23	74.19

[19] *See* World Bank, *New Country Classifications*, http://data.worldbank.org/news/new-country-classifications (last visited Mar. 4, 2014).

[20] The most of the professionals appear to have background related to IPR, bioethics and life science. The patient advocate, physician and ethicist also took part. Since multiple respondents had several professional identity/ affiliation, there were grouping for the purpose of analysis according to the reference of the professions the respondents made.

Academic, Bioethicist & Lawyer	1	3.23	77.42
Academic, Lawyer & Patient	1	3.23	80.65
Bioethicist & Lawyer	1	3.23	83.87
Bioethicist & Researcher	1	3.23	87.1
Lawyer & Scientist	1	3.23	90.32
Patent Examiner & Researcher	1	3.23	93.55
Scientist & Researcher (any field)	2	6.45	100
Total	**31**	**100**	

From the perspective of gender, the respondents are of following number:

Table 5

Gender	Frequency	Percent	Cumulative %
Male	18	58.06	58.06
Female	13	41.94	100
Total	**31**	**100**	

They identify themselves into following age groups:

Table 6

Age Groups (Years)	Frequency	Percent	Cumulative %
Less than & 25	1	3.23	3.23
26-30	8	25.81	29.03
31-35	9	29.03	58.06
36-40	4	12.9	70.97
41-45	2	6.45	77.42
46-50	3	9.68	87.1
51-55	1	3.23	90.32
56-60	1	3.23	93.55
More than 65	2	6.45	100
Total	**31**	**100**	

B. Objectives from the Perspectives of Intellectual Property Protection Of hSCI

The above mentioned course of data analysis was employed to pursue the following objectives:

- To examine if the patent offers the best protection to hSCI;
- To explore if there is any need of new IPR protection framework;
- To find if there will be any benefit of imposing legal obligation on the IPR owner of hSCI; and
- To know if seeking public opinion is necessary to observe the post marketing impact of IPR protection on the health care receiver.

III. Survey Data Analysis

A. Methodology

Responses to the survey questionnaire collected over email were mostly categorical in nature. Respondents were free to choose from the suggested options and/or include their own opinion as well. In order to perform a quantitative analysis, it was, therefore, necessary to code and compile the responses. Microsoft excel was used to compile all the responses into an excel file and this dataset was used to prepare the numerical summary and for further data analysis. Survey numerical summary comprised of frequency distribution table and graphical representation for each variable. This summary served as a good way to consolidate and look at the response pattern at a glance.

As most of the questions were designed in context, we wanted to analyze how the response to one question was related to another and how much it varied among different respondents. Our goal was to look for possible associations of related variables comprising the questionnaire. Some of the variables were hypothesized to be independent and predictor of another dependent or response variable. We, therefore, came up with a predictor-response variable table to check for possible association. This required performing logistic regression analysis in STATA SE 13 software, and in order to do that all the variables with multiple options were converted in the most logical manner into binary responses (STATA code translation).[21]

[21] *Age group split up into 3 binary subgroups:
*Binary code: Ageb (if age of the respondents is 35 years or below)
- Ageb = 1 (35 years or below)
- Ageb = 0 (36 years and above)

*Binary code: Ageb1 (if age of the respondents is 30 years or below)
- Ageb1 = 1 (30 years or below)
- Ageb1 = 0 (31 years and above)

*Binary code: Ageb2 (if age of the respondents is 40 years or below)

- Ageb2 = 1 (40 years or below)
- Ageb2 = 0 (41 years and above)

*Age group as a continuous predictor (non-binary): coded as Ageb3

- Ageb3 = 0 (30 years or below)
- Ageb3 = 1 (31 to 50 years)
- Ageb3 = 2 (51 to 65 years)

*Gender to binary code: genderb

- genderb = 0 (Male)
- genderb = 1 (Female)

*Country economy based on Gross National Income (GNI) to binary code: gnib1(High Economy Group or not)

- gnib1 = 0 (if income is <12616$)
- gnib1 = 1 (if income is > = 12616$)

*Profession split up into 6 binary subgroups:

*Binary code: professionb1(Belong to legal professions or not)

- professionb1 = 0 (if does not belong to the legal profession)
- professionb1 = 1 (if belongs to the legal profession)

*Binary code: professionb2 (Belong to academia or not)

- professionb2 = 0 (if does not belong to academia)
- professionb2 = 1 (if belongs to academia)

*Binary code: professionb3 (Bioethicists or not)

- professionb3 = 0 (if not bioethicist)
- professionb3 = 1 (if bioethicist)

*Binary code: professionb4 (Patient /patient advocate, or not)

- professionb4 = 0 (if not Patient/ patient advocate)
- professionb4 = 1 (if Patient/ patient advocate)

*Binary code: professionb5 (Patent examiner, or not)

- professionb5 = 0 (if not Patent examiner)
- professionb5 = 1 (if Patent examiner)

*Binary code: professionb6 (Researcher, or not)

- professionb6 = 0 (if not Researcher)
- professionb6 = 1 (if Researcher)

*Q6 to binary code: q6b

Do you think patent protection as it exists today is the best way to provide incentive to human stem cell inventions/ innovations?

- q6b = 1 if Yes
- q6b = 0 if No

*Q7 to binary code: q7b

Do you think that a new protection mechanism/ framework can be/ should be developed within the purview of intellectual property law (IPR), separate from patent, for the inventions/ innovations that use biological materials of human origin and targeted to health care?

- q7b = 1 if Yes
- q7b = 0 if No

*Q8 to split up into 4 binary subgroups:

Results of logistic regression analysis were expressed in odds ratio (OR) and two-tailed confidence interval (CI) for each OR assumed an alpha of 0.05.

How many years of protection (term of protection for commercial exploitation) is appropriate for human stem cell inventions/ innovations?

*Binary code for those opting for 20 years of protection: q8b1

- q8b1 = 1 if Yes
- q8b1 = 0 if No

*Binary code for those opting for more than 20 years of protection: q8b2

- q8b2 = 1 if Yes
- q8b2 = 0 if No

*Binary code for those who opt for less than 20 years of protection: q8b3

- q8b3 = 1 if Yes
- q8b3 = 0 if No

*Binary code for those opting for no protection: q8b4

- q8b4 = 1 if Yes (who opted for "No" protection)
- q8b4 = 0 if No

* Q10 split up into 4 binary subgroups:

Who, according to your opinion, should be entitled to the intellectual property rights (IPR) of human stem cell inventions/ innovations?

*Binary code for both scientists and organization: q10b1

- q10b1 = 1 if Yes
- q10b1 = 0 if No

*Binary code for only scientists: q10b2

- q10b2 = 1 if Yes
- q10b2 = 0 if No

*Binary code where respondents think none should own IPR: q10b3

- q10b3 = 1 if Yes
- q10b3 = 0 if No

*Binary code where respondents think only scientists or both scientists & organization should own IPR: q10b4

- q10b4=1 if Yes
- q10b4=0 if No

*Q12 to binary code: q12b

Do you think legal obligation for issuing 'licenses on easy terms' or 'compulsory licenses' and 'technology transfer' can bring benefit to the patients by ensuring availability of medication/ treatment at a reduced cost and may also serve as incentive for the IPR right owner of human stem cell inventions/ innovations at the same time?

- q12b = 1 if yes
- q12b = 0 if No

*Q13 to binary code: q13b

Do you think *public opinion* should be sought and be given importance after the invention/ innovation is put to the market for commercial exploitation, in order to measure the impacts of the IPR protected invention/ innovation on the health care receiver?

- q13b = 1 if yes
- q13b = 0 if No

The following table summarizes the possible associations between the predictor and response variables [22] that were tested using the logistic regression analysis.

Table 7

Predictor Variable	**Binary Predictor Variable**	**Response Variable**	**Binary Response Variable**
Profession	professionb1- b6	Does existing patent protection provide the best incentive? (Q6)	q6b
Profession	professionb1 - b6	Can/Should a new protection framework be developed ?(Q7)	q7b
Profession	professionb1 – b6	What is the appropriate term of protection for commercial exploitation? (Q8)	q8b1- b4
Profession	professionb1 – b6	Who should be entitled to the intellectual property rights? (Q10)	q10b1- b4
Profession	professionb1 – b6	Do you think issuing legal obligation can be beneficial? (Q12)	q12b
GNI group	gnib1	Can/Should a new protection framework be developed ?(Q7)	q7b
GNI group	gnib1	What is the appropriate term of protection for commercial exploitation? (Q8)	q8b1- b4
GNI group	gnib1	Who should be entitled to the intellectual property rights? (Q10)	q10b1- b4
GNI group	gnib1	Do you think issuing legal obligation can be beneficial? (Q12)	q12b
GNI group	gnib1	Do you think *public opinion* should be sought	q13b

[22] The STATA code translations for the predictor and response variables are detailed in footnote 21.

		and be given importance? (Q13)	
Age group	Ageb, Ageb1-3	Does existing patent protection provide the best incentive? (Q6)	q6b
Age group	Ageb, Ageb1-3	Can/Should a new protection framework be developed? (Q7)	q7b
Age group	Ageb, Ageb1-3	What is the appropriate term of protection for commercial exploitation? (Q8)	q8b1- b4
Age group	Ageb, Ageb1-3	Who should be entitled to the intellectual property rights? (Q10)	q10b1- b4
Age group	Ageb, Ageb1-3	Do you think issuing legal obligation can be beneficial? (Q12)	q12b
Age group	Ageb, Ageb1-3	Do you think *public opinion* should be sought and be given importance? (Q13)	q13b
Q6	q6b	Can/Should a new protection framework be developed ?(Q7)	q7b
Q6	q6b	Who should be entitled to the intellectual property rights? (Q10)	q10b1- b4
Q6	q6b	Do you think issuing legal obligation can be beneficial? (Q12)	q12b
Q7	q7b	What is the appropriate term of protection for commercial exploitation? (Q8)	q8b1- b4
Q7	q7b	Who should be entitled to the intellectual property rights? (Q10)	q10b1- b4
Q7	q7b	Do you think issuing legal obligation can be beneficial? (Q12)	q12b

Q7	q7b	Do you think *public opinion* should be sought and be given importance? (Q13)	q13b
Q8	q8b	Does existing patent protection provide the best incentive? (Q6)	q6b
Q10	q10b1- b4	Can/Should a new protection framework be developed? (Q7)	q7b
Q10	q10b1- b4	What is the appropriate term of protection for commercial exploitation? (Q8)	q8b1- b4
Q13	q13b	Does existing patent protection provide the best incentive? (Q6)	q6b

B. Question-Wise Summary
Question 6[23]:

Table 8

Does Existing Patent Protection provide the Best Incentive to human Stem Cell (hSC) based Innovations/Inventions?	**Frequency**	**Percent**	**Cumulative %**
Yes	13	41.94	41.94
No	2	6.45	48.39
No: Complications & uncertainty of enforcement	2	6.45	54.84
No: Inappropriate to reward life science innovations	3	9.68	64.52
No: Invokes exclusive commercialization	3	9.68	74.19
No: Patented hSC	1	3.23	77.42

[23] As it was numbered in the questionnaire.

innovation is a form of commercialization of "Life"			
Other opinion	3	9.68	87.1
No: Inappropriate to reward life science innovations & patented hSC innovation is a form of commercialization of "Life"	1	3.23	90.32
No: Inappropriate to reward life science innovations & other opinion	1	3.23	93.55
No: Invokes exclusive commercialization & patented hSC innovation is a form of commercialization of "Life"	1	3.23	96.77
No: Uncertainty of enforcement, inappropriate to reward life science innovations & patented hSC innovation is a form of commercialization of "Life"	1	3.23	100
Total	**31**	**100**	

Question: 7

Table 9

Need for New Protection Framework	**Frequency**	**Percent**	**Cumulative %**
No	5	16.13	16.13
Yes: Can be	15	48.39	64.52
Yes: Should be	8	25.81	90.32

Other opinion	2	6.45	96.77
No: Other opinion	1	3.23	100
Total	**31**	**100**	

Question: 8

Table 10

Term of Protection for Commercial Exploitation Suggested for human Stem Cell based Invention/ Innovations	**Frequency**	**Percent**	**Cumulative %**
No protection	9	29.03	29.03
More than 20 years	1	3.23	32.26
20 years	9	29.03	61.29
15 years	1	3.23	64.52
10 years	7	22.58	87.1
5 years	3	9.68	96.77
20 or more than 20 years	1	3.23	100
Total	**31**	**100**	

Question: 10

Table 11

Entitlement of the IPR for human Stem Cell based Invention/Innovations	**Frequency**	**Percent**	**Cumulative %**
No one should own IPR	6	19.35	19.35
Scientist/Inventor	3	9.68	29.03
Employer organization/University/Assignee	1	3.23	32.26
Both scientist & employer organization	12	38.71	70.97
State: Through its health care department	4	12.9	83.87
Other opinion	3	9.68	93.55
Scientist/Inventor & patients	1	3.23	96.77
Scientist, employer organization & the State health care	1	3.23	100

department			
Total	**31**	**100**	

Question: 12

Table 12

Benefits of Imposing Legal Obligations (Cost Reduction & Incentives to Innovations)	**Frequency**	**Percent**	**Cumulative %**
Yes	8	25.81	25.81
Yes: If public health care sector involved	9	29.03	54.84
Yes: If licenses issued in favor of local manufacturers	2	6.45	61.29
Yes: But not sure	6	19.35	80.65
Other opinion	4	12.9	93.55
No: May benefit some impoverished countries but not required for every country	1	3.23	96.77
Yes: If public health care sector involved & licenses Issued in favor of local manufacturers	1	3.23	100
Total	**31**	**100**	

Question: 13

Table 13

Seeking Public Opinion: To Measure Post Marketing Impacts of IPR	**Frequency**	**Percent**	**Cumulative %**
No	7	22.58	22.58
Yes	7	22.58	45.16
Yes: Public opinion can be received online	11	35.48	80.65

Other Opinion	6	19.35	100
Total	**31**	**100**	

IV. Key Findings and Observations

A. Survey Numerical Summary

Question 6: Substantial number of respondents (41.94%) thought that the current patent system is working well to offer incentive to innovation for hSCI. The majority rejected the system on various grounds (approximately 49%). 9.68% of the respondents had different opinion.

Question 7: Despite substantial number of respondents (41.94%) thought that the patent system is working well for hSCI, approximately 75% of the respondents were interested to see an IPR protection framework separate from patent for those inventions/innovations that use biological materials of human origin[24] and targeted to health care.

Question 8: 29.03% of the respondents showed inclination towards the patent system, when it comes to the term of protection, as patent typically protects the invention for 20 years. An equal percentage (29.03%) of the respondents were also suggesting "no protection" for commercial exploitation; the mentality seems to be inclined to treat hSCI as "public good" or a freely available resource. A good number of respondents (35.49%) were in favor of endorsing a below 20 years' term of protection for commercial exploitation.

Question 10: 19.35% of the respondents were inclined to view IPR for hSCI as public good, as they did not favor the proprietary nature of the IPR for the hSCI. In question number 8, 29.03% of the respondents suggested "no protection" for those inventions/innovations. It can be observed that at least 19.35% of the respondents (between 19.35% (no one should own IPR

[24] The biological materials (in human) can be derived from the embryo, fetus or fully developed human being. Stem cell based inventions may require the use of human somatic cell, sperm, eggs and embryos for the product development. Although some of them are clearly "biological material of human origin" in the normal sense of the term, not all of them are accepted to be defined in such way by all the stakeholders. Whether, how and which of the stem cell based inventions encompasses the "biological material of human origin" can invite differing opinions. Another question (not included in this article) was asked to the respondents about "embryo destruction for research and invention/innovation" having one of the suggested options addressing the human embryos as the "biological material of human origin." 29.03% (9 out of the total 31) of the respondents treat the embryo as biological material of human origin.

These questions widely attempts to see if the stem cell based inventions, having encompassed the use of biological material of human origin, should be protected under a different IPR framework or not.

of hSCI) and 29.03% (no protection)) do not want that individual or organization should own the IPR of hSCI.

38.71% of the respondents supported the idea of IPR of hSCI being owned by the "scientist and employer organization" which at present happens mostly in the case of patent protection. 12.9% of the respondents supported the invention/ innovation to be owned by the "State: through its health care department" only. Ownership by State is feasible when the funding for research and investment comes from "public" sources. If the research and investment is conducted through "private" funding, exclusive ownership would be an obvious claim and seek justification as "incentive for innovation".

Question 12: At present compulsory licensing is not a precondition of obtaining/granting the patent. In some jurisdiction compulsory licensing can be done under the intellectual property law on certain grounds. There is a great diversity among the countries under which circumstances compulsory licenses can be issued. Article 31 of the TRIPS Agreement provides strict conditions under which "Use Without Authorization of the Right Holder" is possible.[25] It does not allow imposing the "compulsory licensing" on the will of the State authority where the patent is commercially exploited, as a precondition to patent. The affordability of the consumer in a particular territory is not a consideration of that provision. To remedy an anti-competitive effect, the "judicial or administrative" authority can be exercised under Article 31(k).[26] Such use can also be permitted under Article 31(b) for "national emergency or other circumstances of extreme urgency or in cases of public non-commercial use" for a limited duration.[27] But an absence of *consideration of affordability of the consumer* in the legal framework, where public sector does not offer services in non-commercial manner, will not contribute to the wider access to the therapeutic applications of patented inventions. Determination of anti-competitive effects is also restricted to certain fixed criterion.

In this question, the examples of legal obligations were: (1) issuing licenses on easy terms, (2) compulsory licenses, and (3) technology transfer. This question explored if those legal obligations can be beneficial for wider accessibility of the medication in one hand and the intellectual property right of the IPR owner remains unaffected by them on the other hand. "No" and "other opinion" accounted for approximately 17%. However, 83.87%

[25] *See* Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter, "*TRIPS Agreement*"].

[26] *See id.*

[27] *See id.*

respondents supported that legal obligation may contribute to wider access to the therapy and will not harm the intellectual property right of the IPR owner. Reduced cost of the therapy is presumed to contribute to wider access to the treatment.

Question 13: 58.06 % of the respondents believed that public opinion can make a difference. There is post marketing surveillance by the U.S. Food and Drug Administration (U.S. FDA) that is concerned about the consumer responses to the drugs (regarding any adverse reactions) in post marketing months.[28] But the consumers are never informed about the production cost of the drug, the percentage charged for the present and future research and investment, IPR protection and marketing costs, when they are purchasing a drug. The consumer, if they are well informed, might generate sensible information about their affordability and practical implications of pricing on therapy, if such an opportunity is created. No doubt, that IPR protection contributes to enhanced cost of the drugs to a substantial extent. Monitoring and taking into account the public opinion will create an opportunity of people's participation in the cycle of biomedical research. For balancing the drug price, i.e., cost of the therapy and making it affordable to wider number of people, public opinion can be a good resource. It is debatable if the consumers possess enough information and knowledge to make sensible comments, but the patient who undergoes a treatment educate himself/ herself in that process and his/ her first hand experience can also be considered as a source of valuable information.

The above summary is a useful way to see the overall response pattern and also points to the direction subsequent statistical analysis needs to be carried out. However, the limitation of the findings and observations from the survey numerical summary lies in the fact that although the frequency and cumulative percentage in the numerical summary offered insight on how majority of the respondents answered to individual question, this does not necessarily indicate to any association between two variables to be statistically significant. Results derived from logistic regression analysis between different predictor and response variables reflect such associations.

B. Logistic Regression Analysis Using STATA SE 13

A complete "Logistic Regression Analysis Table" and the corresponding "STATA Software Output" are not incorporated into the text of the writing. Only the tables with results showing "Significance" and the results showing "Trend" from those 6 questions have been inserted and interpreted in this

[28] *See* U.S. Food & Drug Admin., *Postmarketing Surveillance Programs*, http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/ucm090385.htm (last visited Sept. 25, 2014).

writing. The p-value has to be less than 0.05 in order to be "significant" (95% significance with alpha level of 0.05). A p-value little more than 0.05 shows a "trend" towards significance.[29]

1. Logistic Regression Output (STATA SE 13): Results Showing Significance

Table 14

Predictor	Response	P-value	Odds Ratio (OR)	95% Confidence Interval (CI)
professionb1	q6b	0.032	5.599999	1.158285 - 27.07451
Ageb3[30]	q8b4	0.342	3.076923	0.3021829 - 31.33021
		0.043	24	1.110724 - 518.5807
gnib1	q7b	0.043	7.6	1.067807 - 54.09217
q8b1	q6b	0.007	12.8	2.019838 - 81.11538
q10b1	q8b1	0.036	5.833333	1.119237 - 30.40265
q10b4	q8b4	0.009	0.046875	0.0047908 - 0.4586413
q13b	q6b	0.024	0.1442308	0.0268644 - 0.7743521

2. Logistic Regression Output (STATA SE 13): Results Showing Trend

Table 15

Predictor	Response	P-value	Odds Ratio (OR)	95% Confidence Interval (CI)
professionb1	q8b4	0.069	0.125	0.0132999 -

[29] The soft copies of the complete "Logistic Regression Analysis Table" and the "STATA Software Output" are provided to the reviewer of the article.

[30] Ageb3 is a continuous predictor having three age groups (non-binary). Compared to the reference group (30 years or below), the change in other two groups are analyzed. Therefore, unlike other results, the change in increasing age is shown by a pair of results. For instance, even though the age group (31 to 50 years) shows a non-significant p-value of 0.342, the more elderly group (51 to 65 years) does show a significant p-value of 0.043.

				1.174819
Ageb2	q8b3	0.097	6.666667	0.7084089 - 62.73841
Ageb3[31]	q10b4	0.178	0.2857143	0.0461565 - 1.768608
		0.094	0.0952381	0.0060564 - 1.497631
q6b	q10b1	0.066	4.16	0.9092842 - 19.03211
q7b	q13b	0.091	5.333333	0.7668501 - 37.09256

3. Interpreting "Significance" and "Trend" in the Logistic Regression Analysis Output

While a statistically significant number of respondents (p-value = 0.007) opting for 20 years of protection for commercial exploitation were also more likely (OR= 12.8; 95% CI OR = 2.019838 - 81.11538) to consider the current patent system as the best way to provide incentive to human stem cell inventions/ innovations, the odds (p-value = 0.032) of preferring the existing patent system were 5.6 times higher (OR = 5.599999; 95% CI OR = 1.158285 - 27.07451) among the legal professionals compared to others. Respondents who opted for "no protection at all" were 95.31% less likely (OR = 0.046875; 95% CI OR = 0.0047908 - 0.4586413) to concur to the idea of entitlement of IPR to "scientists, organization (employer) or both" (p-value = 0.009). Compared to the respondents who belong to 30 years or below age group, those who are between 31 and 50 years old are 3.1 times (OR = 3.076923; 95% CI OR = 0.3021829 - 31.33021) and those who are between 51 and 65 years old are 24 times (OR = 24; 95% CI OR = 1.110724 - 518.5807) more likely (p-value = 0.043) to consider that "no one should own IPR of human stem cell inventions/innovations". Although a statistically significant (p-value = 0.032) result was observed in the case of the most elderly group (51-65 years), the p-value for the age group of 31-50 years (p-value = 0.342) was not significant at an alpha level of 0.05. On the other hand, those who found "20 years (term of protection for commercial exploitation) of protection"[32] appropriate were also 5.83 times (OR =

[31] Age is a continuous variable; therefore, unlike other results, the change in increasing age is shown by a pair of results.

[32] Patent is granted by a State in favor of the patentee/ assignee, empowering the owner (patentee/ assignee) the right (exclusive) to exploit the invention commercially throughout the period of term of protection, which is usually 20 years. Article 33 of the TRIPS Agreement, 1994 provides 20 years' term of protection for patents.

5.833333; 95% CI OR = 1.119237 - 30.40265) more likely (p-value = 0.036) to think that "both scientists and organizations (employer)" should be entitled to the IPR of human stem cell inventions/innovations. For the respondents from high economy country, the odds of favoring a "new protection mechanism/framework, separate from patent," for these innovations/inventions were 7.6 times higher (OR = 7.6; 95% CI OR = 1.067807 - 54.09217) compared to those from middle and low economy countries (p-value = 0.043). In addition, those who consider that "public opinion should be sought" in order to measure the impact of the IPR protected invention/innovation on the health care receiver were 85.57% less likely (OR = 0.1442308; 95% CI OR = 0.0268644 - 0.7743521) to think that the existing patent system are the best (p-value = 0.024).

Logistic regression analyses also revealed some promising associations although they were not significant at an alpha level of 0.05. For instance, the odds of concurring to "no IPR protection at all" for human stem cell inventions/innovations among the legal professionals were 87.5% less compared to those who belong to other professions (p-value = 0.069; OR= 0.125; 95% CI OR = 0.0132999 - 1.174819). In comparison to the respondents who belong to the age group 30 years or below, those who are between 31 and 50 years old have 71% (OR = 0.2857143; 95% CI OR = 0.0461565 - 1.768608) and those who are between 51 and 65 years old have 90.5% (OR = 0.0952381; 95% CI OR = 0.0060564 - 1.497631) less likelihood to consider that "only scientists or both scientists & organization (employer)" should own the IPR. Although the relation observed in the case of the most elderly group (51-65 years) showed a positive trend (p value = 0.094), the effect was statistically not "significant." For the respondents who opted for the existing patent protection, the odds of favoring entitlement of IPR to "both scientists and organizations (employer)" were 4.16 times higher than those who consider otherwise (p-value = 0.066; OR = 4.16; 95% CI OR = 0.9092842 - 19.03211). Interestingly, respondents aged 40 years or below were 6.7 times more likely to find "less than 20 years" of "term of protection for commercial exploitation" (IPR protection) appropriate compared to those who were above 40 years old (p-value = 0.097; OR= 6.666667; 95% CI OR = 0.7084089 - 62.73841). Also those who considered that a new protection mechanism/framework "can be"/"should be" developed were 5.3 times more likely to think that public opinion should also be sought to measure the post-marketing impacts of the IPR protected invention/ innovation on the health care receiver (p-value = 0.091; OR= 5.33; 95% CI OR = 0.7668501 - 37.09256).

V. Conclusion and Recommendations

The survey numerical summary revealed several clear favorite options as chosen by the respondents. In a nutshell, the majority of the participating respondents did not consider that the current patent system offers the best incentive to hSCI on various grounds (approximately 49%); were highly supportive to the idea of a new protection framework (74.2%); did not support 20 years' term of protection (either against any type of protection or consider that less than 20 years of protection for commercial exploitation is appropriate for these type of inventions/innovations) (64.52%) [33]; and thought that imposing legal obligation is beneficial and simultaneously can serve the purpose of cost reduction and encouraging innovation (83.87%) and endorsed seeking public opinion to measure the post marketing impacts of IPR protection (58.06%). The current practice of entitlement of the IPR to both the scientists and organization (employer) was preferred by a substantial number of respondents (38.71%).

The logistic regression analysis reveals statistically significant relationship between:

- preference to the current patent system and supporting 20 years of IPR protection, with the legal professionals being the most prominent ones favoring the current system in place;
- residence in a high economy country and supporting development of a new protection framework;
- older age group (51 to 65 years) and predilection not to support entitlement of these inventions/innovations;
- inclination to opt for 20 years of protection and supporting the entitlement of the IPR (of human stem cell based inventions/innovations) to both the scientists and organizations (employer);
- aversion to the existing patent protection and preference to seeking public opinion in order to measure the post marketing impacts of the IPR protected invention/ innovation on the health care receiver.

In addition, several other promising associations showing positive trend were found.

The following conclusion by way of recommendations can be drawn after this empirical investigation. The numerical summary revealed that 41.94% of the respondents supported the patent system at present conditions and approximately 75% of the respondents will be interested to see a separate IPR protection framework for the inventions/innovations that use biological materials of human origin and has application in health care. This study revealed that the *legal professionals* consider the patent protection as it

[33] "No protection" + less than 20 years of protection = 29.03% + 3.23% + 22.58% + 9.68% = 64.52%.

exists today as the best way to provide incentive to hSCI.[34] Therefore, if we imagine that the patent continues to offer the IPR protection for the hSCI, there can be certain improvisations in the patent system that may contribute to the enhancing of the access to the stem cell based therapy at more affordable costs. 35.49% respondents suggested a *less than 20 years' term of protection* for commercial exploitation. 83.87% respondents thought that there will be benefits in terms of cost reduction and incentives to innovations, if *legal obligations* are imposed. Their choices supporting the legal obligation had additional suggestions such as "involvement of public health care sector (29.03%)" and "issuing license in favor of local manufacturers (6.45%)." 19.35% respondents supported legal obligation but they were *not sure* how it will benefit in "cost reduction and incentive to innovation."

Statistically, this study found that *residence in a high economy country* may prompt respondents to support development of a new protection framework.[35] The study also found that the respondents who are *disinclined to the current patent system*, will support seeking public opinion to observe the impact of the IPR protected invention on the health care receivers.[36] Public consultation may generate ideas to improve the means of accessing the therapy by the patients in respective countries. The study also found that, the respondents of older age group (51-65 years) did not support the entitlement, i.e., the proprietary nature of the IPR for hSCI.[37]

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[34] This conclusion is drawn from the regression analysis output: "a statistically significant number of respondents (p-value = 0.007) opting for 20 years of protection for commercial exploitation were also more likely (OR = 12.8; 95% CI OR = 2.019838 - 81.11538) to consider the current patent system as the best way to provide incentive to human stem cell inventions/ innovations, the odds (p-value = 0.032) of preferring the existing patent system were 5.6 times higher (OR = 5.599999; 95% CI OR = 1.158285 - 27.07451) among the legal professionals compared to others."

[35] Original interpretation: "Respondents belonging to high economy group country (with GNI >= $12,616) would think that a new protection mechanism/framework can/should be developed for the inventions/innovations using biological materials of human origin and directed to health care."

[36] This conclusion is drawn from the findings: "aversion to the existing patent protection and preference to seeking public opinion in order to measure the post marketing impacts of the IPR protected invention/ innovation on the health care receiver."

[37] This conclusion is drawn from the regression analysis output: "Compared to the respondents who belong to 30 years or below age group, those who are between 31 and 50 years old are 3.1 times (OR = 3.076923; 95% CI OR = 0.3021829 - 31.33021) and those who are between 51 and 65 years old are 24 times (OR = 24; 95% CI OR = 1.110724 - 518.5807) more likely (p-value = 0.043) to consider that 'no one should own IPR of human stem cell inventions/innovations'. Although a statistically significant (p-value= 0.032) result was observed in the case of the most elderly group (51-65 years), the p-value for the age group of 31-50 years (p-value = 0.342) was not significant at an alpha level of 0.05."

Offering the IPR protection for hSCI under the umbrella of supranational legal framework can be one way to offer protection. They are better suited for countries with similar socio-economic culture. There is need to have a uniformity in health care policies and similar ambitions in science and innovation among the States in order to enable a supranational legal arrangement to yield its best outcome. If the present scenario of patenting in the EU is taken into consideration, certain observations are worth mentioning. Despite cultural diversity, there are some coherence achieved through European community legislations and some differences remained when it comes to patenting life science based inventions. The feasibility of this recommendation in practical terms remains uncertain. The new Unitary Patent (UP)[38] protection for the EU countries is not accepted by all the States in the EU.[39] Spain has been continuously opposing the UP. As part of the opposition to this new EU initiative, two actions brought by Spain is pending before the CJEU, i.e., Case C-146/13 and Case C-147/13 (*Kingdom of Spain v. European Parliament and Council of the European Union*)[40] challenging the Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection.[41] In Europe, there remains the diverse approach of interpreting the ethical issues involved in hSCR and their patent protection. A new protection mechanism separate from patent under supranational legal framework shall also have to overcome the current obstacles of ethical issues in stem cell research and patenting. Because, the stem cell research as a basic research will remain the same, be it patented or not. Avoiding patent and offering a separate IPR protection will only change features of the commercial exploitation of the invention.[42] There can be meeting of minds between the States that have similar stem cell research policy. But they are going to be States from different continents. Therefore, could TRIPS Agreement offer any IPR protection of hSCI? A new section may be added in the TRIPS Agreement, which will be different from patent, utility model and trade secret protection. But that new provision will have to

[38] Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December 2012 Implementing Enhanced Cooperation in the Area of the Creation of Unitary Patent Protection, Dec. 17, 2012, 2012 O.J. (L 361) 1.

[39] 25 Countries are currently participating in this new EU patent except Croatia, Italy and Spain.

[40] Both actions brought on March 22, 2013.

[41] Dec. 17, 2012, 2012 O.J. (L 361) 1.

[42] Access to the therapy will largely depend on how the invention is commercially exploited. Stricter IPR may result in higher cost of the therapy. Therefore, the features of the IPR protection enabling the commercial exploitation is an important factor for cost reduction and promoting increased access to the therapy.

take into account the economic realities prevalent in developing countries with a goal to ensure wider access to the therapy. It will require lengthy consultation process and the challenges in reaching unanimity on the purview of legitimate stem cell research shall remain ahead.

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