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Use of Artificial Intelligence in Stem Cell Research – Legal, Social and Health Concerns

¹Preetham. B, ²Dr. N. Balu,

¹Research Scholar, SRM school of Law, SRM Institute of Science and Technology. Kattankulathur-603203 Tamil Nadu, India

²Research Guide, SRM School of Law, SRM Institute of Science and Technology, Kattankulathur-603203 Tamil Nadu, India

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	ABSTRACT:		
KEYWORDS	Artificial intelli	gence (AI) is an evolving discipline	with a combination of computer science and
Discipline,	engineering. This innovative invention from its launch has shown latent applications in various fields		
Artificial intelligence,	such as robotics, agriculture, home automation, healthcare, banking, and transportation. Due to		
Predictability,	technological developments AI and its applications have helped scientific researchers to enhance the		
Predictable.	precision and the quality of the output of a products or process. Recently AI has been used in the field of stem cell research. Stem cells are unique cells with an ability to reproduce continuously. This ability of the stem cells and products and process derived from it have promising abilities to		
	cure incurable	diseases. But since it is a natural pro	cess or a stimulated process it is difficult to
	determine the q	uality and the output of the cells. Ste	em cells have concerns in predictability and
	identification of the quality stem cells for research or extraction purposes. Albiet its promising		
	abilities concern	ns were raised regarding its accurate p	redictable use.
	The researcher	in this article has tried to Map the	plausible legal, social and ethical issues in
	including Artifi	cial intelligence to the field of stem ce	lls and the existing National and international
	policy approach	to resolve the conundrums.	

Introduction

"Artificial intelligence is one of the most profound things we're working on as humanity. It is more profound than fire or electricity." – sundar pichai.

Hi Alexa!! Or Hi Siri!! are common terms used by even kids, makes us wonder about the ease and efficiency of the Artificial intelligence in our day to day lives. AI is acknowledged as a profound invention with promising abilities. At the outset AI and its inventions are seen as the greatest boon to the human kind on the other hand it is viewed as pandoras box which has moral and ethical concerns. Specifically, its use in biotechnology is considered unethical as it might lead to life extension , designer babies and AI humanity. The social scholars have raised the question of responsibility for the AI made decisions in the health care Industry. Though the legal uncertainties are not dissuading the application of AI to different fields of like banking, marketing , entertainment , robotics, tourism its application in the health sector especially in stem cell research has raised concerns .

The researcher has done an exploratory study to understand and highlight the plausible applications of the stem cell research in the first part of the article and its patentability, legal, social, ethical concerns and the existing national and international regulations to regulate the application of AI in the health sector are discussed in the the second part of the article.

Evolution of Artificial Intelligence

The Tin wood man character in wonderful wizard of OZ wishing for heart to have human emotions is the perfect corelation that can be made with the evolution of modern-day Artificial intelligence. In the early 1940's and 1950's after the second world war the desire to integrate machine, automation and intelligence led to development of AI. Mathematical and computer model of the biological neuron (formal neuron) was created by

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Warren McCulloch and Walter Pitts in 1943¹. In 1950, John Von Neumann and Alan Turing who are considered to be the founding fathers have made significant contributions to the field of AI ². The coining of the term Artificial intelligence is attributed to John McCarthy of MIT. But in the initial stages as the machines had very little memory it was difficult to use as a computer language and the popularity of AI took a backstage until the AI Deep Blue (IBM's expert system) defeated the chess champion Garry Kasparov at the chess game in 1997. With the development of big data and the new power computing AI became the limelight after 2010. With more R& D funds and innovative technological developments boosted the innovations in Artificial intelligence³.

Defining Artificial Intelligence:

Marvin Minsky defined AI as "the construction of computer programs that engage in tasks that are currently more satisfactorily performed by human beings because they require high-level mental processes such as: perceptual learning, memory organization and critical reasoning"⁴. Artificial intelligence is also addressed as "systems that display intelligent behaviour by analysing their environment and taking actions with some degree of autonomy to achieve specific goals".

John McCarthy popularly known as the father of AI, defines AI as "the science and engineering of making intelligent machines, especially intelligent computer programs. It is related to the similar task of using computers to understand human intelligence, but AI does not have to confine itself to methods that are biologically observable."⁵

In short it can be defined as system designed to mimic human emotions, think, create and innovate like human beings.AI-based systems can be purely software-based, acting in the virtual world like voice assistants, image analysis software, search engines, speech and face

¹ History of Artificial intelligence, council of Europe, <u>https://www.coe.int/en/web/artificial-</u>

intelligence/history-of-ai ² Ibid.

³ Rockwell Anyoha, The History of Artificial intelligence – can machines think?, 28th August 2017, <u>https://sitn.hms.harvard.edu/flash/2017/history-</u> recognition systems . It can also be embedded in hardware device like advanced robots, autonomous cars, drones or Internet of Things applications. Based on the capacity and its integration AI's can be classified as strong and weak. Strong AI requires an intelligence similar to humans and it has the ability to solve problems and plan for the future. But the AI have to learn through the input experiences and gradually gain advanced abilities⁶. Whereas weak AI's focuses on performing a specific task at a given time with human intervention. Hence for advanced scientific research strong AI will be helpful. There are subfields to the study of AI. Machine learning and deep learning subfields of AI are used in the field of stem cell research . The Machine learning model requires human intervention to segment data in to categories and through deep learning with the help of artificial neural network the patterns in the given set of data is identified and used for obtaining the desired accurate results after pertaining it to high volume of training⁷.

Use of AI in stem cell research.

Stem cells are special cells that have the capacity to undergo multiple cell division and the capability to differentiate in to any type of cell. Based on the potency and the place of derivation stem cells are classified in to Embryonic stem cells, Adult stem cells, Induced pluripotent stem cells, Mesenchymal stem cells, Haematopoietic stem cells. Amongst them Embryonic stem cells an important source of regenerative medicine as the stem cells are obtained from the blastocyst or spare embryos in their early stages⁸. With the advent of the artificial technology unique quality of each and every stem cell is put to optimum use for precision-based results in the biomedical research.

In stem cell research deep learning is used for obtaining accurate and automated analysis of cell culture. Deep learning networks are enabled to learn higher-level representations of data without the need for manual

⁵ John Mccarthy, Artificial intelligence, <u>http://jmc.stanford.edu/artificial-</u>

- intelligence/index.html
- ⁶ Ibid.
- ⁷ Ibid.

⁸ Nichols, J., & Smith, A. (2011). The origin and identity of embryonic stem cells. *Development*, *138*(1), 3-8.

artificial-intelligence/ visited on 20-09-2023. ⁴ Ibid.

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features of engineering ⁹. "A commonly used deep learning architecture specialized for image classification is the convolutional neural network (CNN). It performs mathematical operations to translate an image of pixels into so-called feature maps, which represent visual features like edges and shapes. Several convolutional layers can be stacked on top of each other, each taking the previous map as input, such that the CNN learns higher-level features that are more informative for image classification"¹⁰. However based on the nature of the stem cells artificial intelligence is used in its different context. Deep learning networks are enabled to learn higher-level representations of data without the need for manual features of engineering ¹¹.

Generally human embryonic stem cells are obtained from blastocyst as the state of pluripotency can be maintained indefinitely¹². "Cell lines express many markers that are common to pluripotent and undifferentiated cells, such as CD9, CD24, octamerbinding protein (Oct-4), Nanog, alkaline phosphatase, LIN28, Rex-1, Cripto/TDGF1, DNMT3B, SOX2, EBAF, and Thy-1, as well as stage-specific embryonic antigen-3 and -4 (SSEA-3 and -4) and tumor-rejection antigen-1-60 and -1-81 (TRA-1-60 and -1-81)¹³Basic research on human prenatal development and toxicological testing of drugs and environment chemicals stem cells prove to be useful".14.hESC is important for toxicity studies. Using time lapsed videos biologists have analysed the apopolyctic behaviour of the stem cell clusters. using manual means of observation and analysis has human limitations of accuracy, uncertainty and

confusion. Further the repeatability of tests are necessary for confirmation but the number of tests can be limited only. Whereas use of Artificial intelligence in image analysis increases the probability of repeatability of the tests till confirmation . The deviations will be less, unbiased, higher throughput and it can be processed and monitored in a controlled mechanism. The image below explains the processing and the advantages and disadvantages of using Artificial intelligence automated process .

In biomedical research the process of analysing the and verifying cell marker expressions, cellular morphology and its functionality is a daily routine done with experimentally with microscopic inspections but the process is costly, time consuming and requires high trained specialists. CRISPR-Cas9 gene-editing tools are used to control iPSC organization and researchers have managed to develop iPSCs in to various types of cell including 3D printing.

Recently a humanoid robotic AI system that can plan and execute experiments to develop optimized protocol for differentiation of stem cells in to the requisite cell type. The system tested cell culture condition for differentiation of iPSCs in to retinal pigment epithelial cells (RPE)¹⁵. This transformation is based on the optimized protocol and the input data received through image analysis of the pigment producing cells. This can be considered as a major breakthrough in the stem cell research using AI. The AI system was able to develop 143 different conditions from 200 million combinations in 111 days and achieved 88% better iPSC-RPE cells and

⁹ Grafton, F., Ho, J., Ranjbarvaziri, S., Farshidfar, F., Budan, A., Steltzer, S., ... & Mandegar, M. A. (2021). Deep learning detects cardiotoxicity in a high-content screen with induced pluripotent stem cell-derived cardiomyocytes. *Elife*, *10*, e68714.

¹⁰ Marzec-Schmidt, K., Ghosheh, N., Stahlschmidt, S. R., Küppers-Munther, B., Synnergren, J., & Ulfenborg, B. (2023). Artificial intelligence supports automated characterization of differentiated human pluripotent stem cells. *Stem Cells*, *41*(9), 850-861.

¹¹ Grafton, F., Ho, J., Ranjbarvaziri, S., Farshidfar, F., Budan, A., Steltzer, S., ... & Mandegar, M. A. (2021). Deep learning detects cardiotoxicity in a high-content screen with induced pluripotent stem cell-derived cardiomyocytes. *Elife*, *10*, e68714.

¹² Guan, B. X., Bhanu, B., Talbot, P., & Lin, S. (2014). Bio-driven cell region detection in human embryonic

stem cell assay. *IEEE/ACM transactions on computational biology and bioinformatics*, 11(3), 604-611.

¹³ Mimeault, M., & Batra, S. K. (2006). Concise review: recent advances on the significance of stem cells in tissue regeneration and cancer therapies. *Stem cells*, *24*(11), 2319-2345.

¹⁴ Thomson, J. A., Itskovitz-Eldor, J., Shapiro, S. S., Waknitz, M. A., Swiergiel, J. J., Marshall, V. S., & Jones, J. M. (1998). Embryonic stem cell lines derived from human blastocysts. *science*, 282(5391), 1145-1147.

¹⁵ Kanda (2022) "<u>Robotic search for optimal cell</u> <u>culture in regenerative medicine</u>." *eLife* 11:e77007 <u>https://doi.org/10.7554/eLife.77007</u>

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the cells were better than their earlier counterparts. The image below mention in detail the use of AI in stem cell processing and the advantages and disadvantages of using the Manual and AI method of processing the data in stem cell research.



Figure 1: source ¹⁶

Kanda states that systematic, unbiased experiments and suggestions will have immense use in medicine and research¹⁷. Though the use of AI in stem cell research have so far resulted in positive creations and with the advent of the xenobots, the first living cell machines created from frog stem cells and the day we witness them created form human stem cells is not afar. In a recent article edited by Arti Rai, the concept of "organoid intelligence" (OI) is introduced by the researchers. It is defined as a field where the definition of biocomputing to brain directed OI computing¹⁸. Though it is in nascent stages of development it promises remarkable development in human brain information analysis. Novel technology has also raised the concerns of patentability. When an invention or product or process is created without human inventions it raises the concerns

of AI inventorship and the patentability of AI generated creations¹⁹.

Patentability of AI technology in stem cell research Patents are monopoly rights that are granted for scientific inventions that fulfil the patentability criteria of novelty, inventive step and Industrial application and does not fall within the non-patentable subject matter. How ever the patentability of stem cells and its products derived from human beings is controversial subject matter , the addition of AI technology has further created a haze in patenting these technologies . The patent landscape on AI related patents, and AI generated inventions is not uniform across all jurisdictions. The concerns in patentability of AI can be classified in to two types. 1.Patentability of AI technology 2. Patentability of generated invention . The image below shows the details of the AI patent applications filed from 1998 to 2017.

 ¹⁶ Sujith Sebastian(2022) Cell Culture: Implementing robotics and artificial intelligence *eLife* 11:e80609.
¹⁷ Ibid.

¹⁸ Ibid.

¹⁹ Ibid.

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Figure -2 The patent landscape on the number of AI related invention applications filed year wise. Source ²⁰

AI techniques such as deep learning, neural networks, bioinsppired techniques, classification, rule based learning, unsupervised learning and fuzzy logic have been granted patents. The neural networks associated with machine learning technique have been associated with the largest amount of patenting seconded by the bio inspired techniques inclusive of genetic algorithms and particle swarm optimisation²¹. In India AI technology patents are processed similar to the CRI (computer related inventions). In India computer programmes perse are not patentable. It has to fulfill section 3(k) condition. The Delhi Highcourt while determining the patentability

of CRI invnetions held that section 3k restrict Patentability of Computer programmes per se and not on all computer based or related inventions. Innovation in AI, block chain technology and its patentability is dependent on the effect of the programmes.²² The reports form MEITY, NEGD, NASSCOM state that in India more than 70% of the patent applications were on emerging technologies out of which 7% of the applications were related to AI²³. In united states patent no US11531844B2 was granted in Dec 2022 for using machine learning and or nueral networks to validate stem cells and their derivatives (2-D cells and 3-D Tissues for

²⁰ Artificial intelligence a worldwide overview of AI patents and patenting by the UK AI sector (2019), UKIPO, ISBN 978-1-910790-61-8

²¹ Ibid.

²²(WP (C) 7/2014 & CM APPL. 40736/2019)- "Section 3(k) has a long legislative history and various judicial decisions have also interpreted this provision. The bar on patenting is in respect of `computer programs per se....' and not all inventions based on computer programs. In today's digital world, when most inventions are based on computer programs, it would be retrograde to argue that all such inventions would not be patentable. Innovation in the field of artificial intelligence, blockchain technologies and other digital products would be based on computer programs, however the same would not become nonpatentable inventions – simply for that reason. It is rare to see a product which is not based on a computer program. Whether they are cars and other automobiles, microwave ovens, washing machines, refrigerators, they all have some sort of computer programs in-built in them. Thus, the effect that such programs produce including in digital and electronic products is crucial in determining the test of patentability."

²³ Current scenario of artificial intelligence and patent protection in India (2021), <u>https://rnaip.com/current-scenario-of-artificial-intelligence-and-patent-protection-in-india/</u>

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use in cell therapy and tissue engineered products. The patents on AI have increased dramatically in the last 6 to 7 years.

In the recent years AI have been trained to create inventions, creations etc. resulting in patent and copyright applications filed before the different patent and copyright offices claiming AI as authors and inventors challengeing the traditional concept of granting IP protection to Natural persons. In United states in the case of *Beech aircraft corp* $v EDO^{24}$ the court held that Inventors can only be natural persons. The same was upheld in the case of Univ. of Utah v. Max-Planck-Gesellschaft²⁵. In the case of Thaler v hirshfeld ²⁶ The USPTO rejected the patent application stating that AI cannot be listed as inventor in the Patent application and the term inventor cannot be extended to machines. The US court upheld the opinion of USPTO . Thaler had approached different jurisdictions to get patents for his invention DABBUS and it was rejected in EU, UK, and was granted in South Africa and Australia. Australian court in the case of Thaler v Commissioner of Patents²⁷ has given a contradicting opinion interpreting the term "inventor" as an agent noun that is not limited to a person but extends to anything that invents. Based on this interpretation for AI generated inventions, AI's can be considered as inventors.

However the liabilities and responsibilities that come along with granting inventor status is still ambiguous. Further recognising of AI as artificial persons, granting citizenship status has raised legal and ethical concerns in determining the personality status of the AI and its use in the fields of healthcare.

Legal and ethical concerns In using Artificial intelligence in stem cell research

"We must address, individually and collectively, moral and ethical issues raised by cutting-edge research in artificial intelligence and biotechnology, which will enable significant life extension, designer babies, and memory extraction."- Klaus Schwab

²⁶ 558 F Supp.3d 238 (2022)

Science and technology has always helped in finding solutions during difficult situations even during Covid the therapy procedures using mesenchymal stem cell technologies were introduced but due to ethico legal concerns and varied technology policy approach though it was introduced at the time of utmost necessary after overcoming the dire situation the technology policies and approaches changed. It is necessary to have a strong technology policy considering the pros and cons of introducing modern technologies in health care. Scholar Sheila Jaznoff criticises the modern attitude that difficult technological decisions are always resolvable with further research but the difficult part of the decision is mostly political and ethical and not scientific²⁸. Public oppositions, ethical concerns moral objections has not solely banned scientific research despite of the ambiguous outcome. When it is proved beyond doubt that the science per se is dangerous has dangerous outcomes the legislative policies have prevented them from commercial exploitation but have permitted for the purpose of research and its clinical trials. Artificial intelligence and its use in stem cell research is also at the point of 'technological determinism'.

Scholar Jasnoff states that technology is very anthropogenic in nature and is embedded with human values and it requires intentional and unintentional value ladden. Hene it is very important to bridge the gap between the professions of law, medicine with an understanding of the fundamental importance. The most common form of AI used AI in stem cell research is Machine learning. It has two approaches to machine learning which can be classified as supervised and unsupervised learning²⁹. In the Supervised learning system use Artificial Neural Networks (ANNs) which are trained by ANN inputs of images tagged with human outputs there by creating a Data set. Where as in the unsupervised set up there is no training data the AI has to decide and make the decision on its own. If the data input set is not truly representative of the task required

²⁴ <u>990 F.2d 1237, 1248</u> (Fed. Cir. 1993))

²⁵ 734 F.3d at 1323

²⁷ [2021] FCA 879 (Austl.).

²⁸ DanielJ.Rozel (2020) dangerous science : science policy and risk analysis for scientists and engineers. ubiquity press.

²⁹ Ethics of artificial intelligence : Issues and initiatives European parliament research service, March 2020. <u>https://www.europarl.europa.eu/RegData/etudes/STU</u> D/2020/634452/EPRS_STU(2020)634452_EN.pdf

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the AI will exhibit bias³⁰. The use of AI is to remove human bias, but the plausibility of the error remains. Further there are possibilities of wrong identification of the images. For example there might be wrong identification of a car against a snowy backdrop and the ANN has learned to identify the snow backdrop as wolves rather than the wolf itself³¹.

In stem cell research mostly deep learning and machine learning is used to identify images, and there are plausibility's of bias and errors. Carl Simon a biologist at the National Institute of standards technology state that " It is notoriously difficult to characterize cell products as they are not stable and they are not homogenous and the test methods for characterizing them have large error bars"32. Further in case of unsupervised learning there are limitations like slow learning than human beings and require more trials compared to human beings. It raises the concerns of autonomy, intentionality and responsibility. Scholar Sullins state that machines are not under the direct control of any other agents. AI's are not under human control and autonomously make decisions , hence in case of the outcome the fixing of responsibility for the negligence, crimes, violation of human rights is a serious legal concern. It is necessary to fix responsibility for the actions of the AI. Scholar Allen states that the machines have social role and responsibilities³³.

Intentionality states that AI should not morally harmful or beneficial and the actions are seemingly deliberate and calculated. So it is essential that it AI's must be created with beneficial interest and not with harmful intention. Based on the trolley case principle the person who controls the trolley is the ethical producer and whether the producer and data writers can be held liable for the mistakes of AI. When using an AI agent, an undesirable consequence may be caused by the programming codes, entered data, improper operation, or other factors Timmermans addresses this concern as " the problem of many hands" which further creates ambiguity. Scholar karen mills state that privacy and surveillance, bias and discrimination and the role of human judgement are the three major ethical concerns relating to AI applications

³² <u>https://www.nist.gov/news-</u>

that are trying to replace human beings. Further the AI technology also poses questions for both civil and criminal law, particularly whether existing legal frameworks apply to decisions taken by AIs. Pressing legal issues include liability for tortious, criminal and contractual misconduct involving.

Responsibilities and liabilities of AI

The legal Conundrum AI market is expected to add more than \$15 trillion to the global economy by 2030. Despite of its growing demand the AI inventions have raised plethora of concerns attached with its creation, functioning, output, infringement, legal liability and legal responsibility. Granting legal status and citizenship is embedded with legal rights and legal responsibilities. The primary concerns raised is the legal rights available to Artificial intelligence.

In case of inventions it is the right of the inventor to have monopoly for 20 years after obtaining patents. Within this time period if the right to exclusive use, economic exploitation is affected then the inventor can sue and be sued. In case of AI the legal rights regarding the right to sue is still ambiguous. AI evolves by learning overtime. There are chances that AI can infringe the Patent rights of other inventors in the learning process and its utilization. The concern on who should be held liable for infringements committed by AI is also ambiguous. In the case of TC Heartland LLC v. Kraft Food Group Brands LLC.³⁴ The U.S supreme court the concerns in choosing the venue was witnessed. In case of AI it will be difficult to determine. Whether the existing principles of Nationality, effect theory will be adequate is a moot point.

In case of determining criminal liability it is essential to establish '*Actus reus*' and '*mens rea*'. In case of AI though the Act may be committed by AI. Scholar King states that Existing liability models may be inadequate to address the future role of AI in criminal activities³⁵. Macalister states that the actions of autonomous robots could lead to the actus committed by robot and the '*mens rea*' can be equated to that of human manifests. Hallevy states that existing legal models can be split in to three.

³⁰ Ibid.

³¹ Ibid.

events/news/2019/11/stem-cells-and-ai-bettertogether

³³ Ibid.

³⁴ 200 U. S. 321, 337

³⁵ Bathaee, Y. (2017). The artificial intelligence black box and the failure of intent and causation. *Harv. JL & Tech.*, *31*, 889.

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- 1. Perpetrator via another
- 2. Natural probable consequence
- 3. Direct liability

Perpetrator via another model – If a person or entity lacks the capacity for mental capacity for '*mensrea*'. When an innocent agent is instructed by another to commit a crime the person who has instructed will be held liable. As per this model AI can be considered as an Innocent but the creator of the programme shall be considered as the instructor on whose commands the AI functions. Hence the instructor will be held accountable for the Act of AI Natural probable consequence - In case of criminal acts , accomplice will also be held liable for conspiracy. This can be corelated to the misappropriated AI. The programmer, the vendor, the service provider, or the user who has misappropriated can be held liable.

Direct liability - In this model 'actus reus' and 'mens rea' both can be attributed to AI. Kingston gives an example of autonomous cars direct liability for speed limit violation if it has violate the speed limit. In case of strict liability model 'mens rea' is not always attributable. He also claims concern in case of virus attack can be treated similar to intoxication, coercion or malfunction. It is difficult to fix the liability of AI for criminal activities with the existing liability model, there is a requirement to develop a model to fix liability on AI or its creators which has more complex elements other than the two basic tenets of criminal liability.

In 2017 the European parliament Resolution on AI, the resolution fixes responsibility on the human actors . In 2023 EU passed the first AI Act which has proposed set of regulations for AI industry. Title III of the EU AI specific rules for AI systems that create a high risk to the health and safety or fundamental rights of natural persons. The AI permitted will be based on the risk-based approach. Article 9 of the Act has introduced the concept of Risk management system . Art 9 (2) insists on "a continuous iterative process run throughout the entire lifecycle of a high risk AI system with 4 steps of identification and analysis of the known foreseeable risks associated with each high risk AI system and estimated

evaluation of risks that might arise with intended purposed and under conditions of reasonable foreseeable misuse.EU parliament resolution civil liability for AI – The resolution states that there is no need for complete revision of the liability regime. The resolution reiterates the "product liability model".

Similarly countries have different approaches to AI governance. In united states white office of science and Technology oversees the National AI strategy. Singapore has created National AI office to coordinate the implementation of its national AI strategy. Austria has created a council on Robotic and AI. Similarly Canada, Spain, U.S have council for AI. Germany, Singapore, New Zealand and UK have established data ethics committees and rules for creation of AI ³⁶. The National Institution for Transforming India (also known as 'NITI Aayog'), a government-run think tank, has been tasked with producing a national AI policy³⁷. State of Tamil Nadu in 2020 has drafted the safe and Ethical Artificial influence policy which addresses concerns even relating to misuse and ethical principles for creators and users of AI. It is undeniable fact that AI is slowly becoming an integral part of the technological revolution and the countries have adopted different approaches to address the concerns though there is no uniform approach, in future there might be a single unified approach to address the liability concerns relating to AI.

Conclusion

"The real question is, when will we draft an artificial intelligence bill of rights? What will that consist of? And who will get to decide that?"- Gary scott

The policy approaches towards regulating the rights of the Artificial intelligence has evolved and as stated by Garry Scott in future we may witness the bill of rights drafted for artificial intelligence. In the current scenario after analysing it is not appropriate the fix the liability or responsibility on Artificial intelligence. It will pave way for the producers and creators of AI to evade their liability and responsibility and blame it as machine error. The researcher is not in agreement with the policy

³⁶ Galindo, L., K. Perset and F. Sheeka (2021), "An overview of national AI strategies and policies", Going Digital Toolkit Note, No. 14, <u>https://goingdigital.oecd.org/data/notes/No14_ToolkitN</u> <u>ote_AIStrategies.pdf</u>

³⁷ Marda Vidushi, 2018Artificial intelligence policy in India: a framework for engaging the limits of data-driven decision-making*Phil. Trans. R. Soc A.***376**2018008720180087http://doi.org/10.1098/rsta.20 18.0087

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approach of granting the rights to Artificial intelligence and considering AI as inventors and creators it will forfeit the whole idea of the right of monopoly rights guaranteed through the IP regime. The IP regime facilitates economic exploitation through monopoly as a reward or an appreciation to the creator which is not required for an AI. The human beings behind the inventions and the creations are the sole benefactors , hence the fixing of the liability must also be on the inventors. AI may aid the processes but should not be the sole decisive authority especially in the fields healthcare In addressing the ethical concerns of its usage in image analysis, the results must be subjected to human analysis . The existing policy approaches to address the concerns are diverse and there is no uniform approach which will facilitate the interested parties to forum shopping. The resolving of legal uncertainties requires uniform principles and approaches which will pave way for better management of AI related inventions and its impact on the society.