

Young Scientists of Alana v. Republic of Alana
&
Science for Society v. State University of Science and Technology

1. The Republic of Alana is a democratic and secular country situated in the Southern part of the Asian Sub Continent and is federal in nature. The Constitution and laws of the Republic of Alana are in *parimateria* to the laws of India.
2. ‘Science for Society’ (hereinafter referred to as SFS), a group of independent scientists who develops innovative technologies and shares the fruits of the same for the benefit of humankind. They incorporated a company, in the name “Science for Society, Pvt. Ltd.” in the year 2013, in the State of Maple, which is situated in the Southern tip of Alana. The main aim of SFS is to channelise the research activities on human genome for the benefit of humankind. A gene editing technology was developed by them in the year 2015, which resulted in the development of efficient and reliable ways to make precise, targeted changes to the genome of living cells. The details of the newly invented technology were published in a reputed international scientific journal, “Scientifically Speaking”.
3. The said technology, which they named as ‘ujjeevan’*was experimented on animal models of human disease and found out that the technology can be effective in correcting medically incurable genetic defects. Thus, ‘ujjeevan’ was identified to have the potential to transform medicine, enabling not only the treatment, but also prevention of many dreadful diseases such as Malaria, Cancer, HIV AIDS, Zika, and various hereditary diseases. These findings were further published by the 2016 October issue of “Scientifically Speaking”. It has generated tremendous interest around the globe because of the ways ‘ujjeevan’ can be used to develop new therapies aimed at improving human health.
4. Knowing about the merits and the impact ‘ujjeevan’ can make over healthcare sector, a team of professors and experts from the State University of Science and Technology (hereinafter referred to as SUST), funded by the State of Troy, a state in the Republic of Alana, approached SFS with a plan for a collaborated research in utilising the benefits of ‘ujjeevan’ for therapeutic application in human beings.
5. After a series of discussions, on January 22, 2017, SUST and SFS entered into an agreement for the transfer of ‘ujjeevan’ (hereinafter referred to as Technology Transfer Agreement or TTA). One important clause mentioned in the Agreement was that SUST will not use ‘ujjeevan’ for any purpose other than which is specifically agreed upon by the parties. (Relevant clauses of the TTA are extracted in Annexure-1).

6. Scientists from SUST decided to experiment this technology in human embryos for the first time in the world. In their press statement released on Dec 10, 2018, the experts from SUST claimed that they have successfully identified the potential of 'ujjeevan' technology in curing infertility. They also claimed that ten couples have volunteered and consented to participate in the research.
7. Meanwhile, Alana Council of Medical Research (ACMR) and Department of Biotechnology (DBT), Government of Alana, had prohibited Gene Editing in human beings other than for therapeutic purposes through the "National Guidelines for Research in Gene Editing, 2018" (hereinafter referred to as the Guideline). As per the said Guidelines, dated November 18, 2018, Alana allows restricted research involving animals and plants for certain purposes only. (Relevant provisions of the Guidelines, 2018 are extracted in Annexure 2).
8. Upon the apprehension that SUST may misuse 'ujjeevan' detrimental to the interests for which it was created, SFS wrote a letter to the SUST to specify the kind of research SUST was undertaking on 'ujjeevan'. SFS claimed that the actions of SUST are contrary to the agreements made between them. SUST did not reply to the queries of SFS and instead, they called a press meeting on December 28, 2018, and explained that they have created a new technology, 'ujjeevan 2.0', which is a modified and upgraded version of 'ujjeevan'. SUST also claimed that 'ujjeevan 2.0' is essentially different from 'ujjeevan' and the anticipated uses and application of the technology is also different from that of 'ujjeevan'. However, SUST did not bother to explain the kind of research they were conducting with 'ujjeevan'.
9. On the very next day, SFS called a press meet in Maple and shared their apprehension that 'ujjeevan 2.0', which is developed by SUST would not only allow editing of the genes to cure hereditary diseases, but also helps in creation of genome edited embryos with specific traits and characters. They also shared their apprehension that it will also enable the future parents, with the help of infertility experts, to change the genomes of their future children which allows inclusion of the traits they want their offspring to have and to exclude the unwanted negative traits, which is nothing but genetic mutation.
10. This triggered controversy in the Republic of Alana. Popular media like newspapers and TV channels discussed their view points, information and knowledge about the harmful after effects of 'ujjeevan 2.0'. The technology was opposed by the religious and scientific communities alike. Despite strong opposition, the scientists went on with the experiments.
11. SFS served a legal notice on January 28, 2019, to SUST stating that they have violated the provisions of the TTF, especially, clauses 5 and 6. A reply notice was sent by SUST on February 13, 2019 explaining that they have not violated the provisions of the agreement, and being a State University, they were trying to fulfil their fundamental duty of developing scientific temper and spirit of inquiry.
12. Meanwhile, on May 2, 2019, to the shock of everyone, including SUST, Prof. (Dr.) John Honai, a renowned scientist of SUST, who was also involved in the project 'ujjeevan 2.0'

wrote in a blog “How fascinating the world would be, if we could create babies with all wonderful qualities!”. He also mentioned that the world need not wait for long to see the miracles science has kept in reserve. This once again triggered the controversy and student upheaval in SUST. After a week, in a press release given by Prof. Honai, he claimed that his experiments have found its results and he created a baby boy (whom he named ‘Techno’) with the help of ‘ujjevan 2.0’. He explained that the “eggs and sperms were procured from the donors and with the help of a surrogate woman, he was able to create his dream child. He used preimplantation gene editing technology and the baby born has night vision like cats, sense of smell like dogs, and speed and accuracy like cheetah”.

13. SFS approached the High Court of Maple invoking the Writ jurisdiction to prevent SUST from further proceeding with the research and clinical trials. SFS alleged that the SUST is researching on and practicing gene editing in human beings, which has resulted in gene mutations. The research carried on by SUST is against public policy and violative of human rights and human dignity. It is also against the Guidelines issued by ACMR, which prohibited genome editing in human beings other than for therapeutic purposes.
14. Meanwhile, upon the revelation of Prof. Honai, SUST released a press note disowning the findings of Prof. Honai and clarified that his research was conducted outside of their campus, and they were unaware of the research, its nature and outcome. The University also revealed that a committee was constituted to probe into the matter. SUST initiated disciplinary proceedings against Prof. Honai and suspended him as he was a regular employee of the University, and was actively involved in developing ‘ujjeevan 2.0’. SUST condemned the research and experiments which are totally against the ethics and ideologies of the University.
15. A group of young scientists, Young Scientists of Alana (hereinafter referred to as YSA) approached the Hon’ble Supreme Court of Alana praying to issue orders prohibiting such scientific experiments in human beings, and seeking *locus standi* also on behalf of ‘Techno’ and other similar babies who may be born into this world with genetic modifications and genome mutations.
16. Considering the inter relationship and gravity of the issue, The Supreme Court of Alana ordered for transferring of the case filed by SFS against SUST in the High Court of Maple. The Supreme Court decided to hear all these matters together on ----- and has issued notice to the parties involved. The Supreme Court would hear the matter on the following issues:
 - a. Maintainability of the Petition before the Supreme Court of Alana.
 - b. *Locus Standi* of the YSA to represent ‘Techno’ and the future generation yet to be born.
 - c. Genes edited using ‘ujjevan 2.0’, which incorporates CRIPR-Cas9 technology, could be passed over to the future generations, thereby altering the genetic make-up of human species.
 - d. Gene editing will result in gene mutations which will affect the ‘quality and dignity’ of ‘human life’.

ANNEXURE- I

Excerpts from the Technology Transfer Agreement (TTA) signed between Science for Society (SFS) and the State University for Science and Technology (SUST) on January 22, 2017.

3. Application of ‘Ujjeevan’

3.1. SUST can make use of ‘ujjeevan’ for ameliorating, treating, preventing, or curing human diseases.

5. Permissible Research

5.1 Since the editing done to the targeted cells can be passed on to subsequent generations, using “ujjeevan” technology to make genome edits has to be done cautiously, and be limited only to cure diseases.

5.2 Genome editing should be done only on genes that lead to serious diseases and only when there are no other reasonable and alternative treatment is available.

5.3 Genome editing may make changes that could fundamentally affect future generations. Therefore, the experiments shall be limited only for therapeutic purposes and should be resorted only for correcting genetically inherited diseases.

6. Prohibited Research

6.1 Research or application of “ujjeevan’ should not cause any adverse impact on ecology and humankind.

6.2 ‘Ujjeevan’ shall not be used as an enhancement tool for human characteristics by modifying or manipulating human genome.

6.3 Any experiments which may lead to genetic mutations shall be prohibited.

6.4 SUST shall not resort to Heritable (Germline) Genome Editing.

ANNEXURE- II

Excerpts from the “National Guidelines for Research in Gene Editing, 2018”, published by the Alana Council of Medical Research (ACMR) and Department of Biotechnology (DBT), Government of Alana, dated, November 18, 2018.

2. Interpretation

- 2.1. Human Genome: An organisms complete set of genetic material encoded in its DNA.
- 2.2. Human Genome Editing: The process of making precise additions, deletions, or alterations to a person’s genome.
- 2.3. Germline Cells: Reproductive cells like sperm and eggs, and the cells from which they develop.
- 2.4. Heritable (Germline) Genome Editing: The process of editing a person’s reproductive (germline) cells, which could impact the children as well as future descendants of the individual receiving treatment.

4. Ethical Principles to be followed

While using any technology for gene editing, following principles are to be observed:

- 4.1. Promoting well-being, i.e., principles of beneficence and nonmaleficence.
- 4.2. Transparency, i.e., openness and sharing of information in ways that are accessible and understandable.
- 4.3. Due Care i.e., The principle of due care for patients enrolled in research studies or receiving clinical care requires proceeding cautiously, deliberately, and incrementally and only when supported by sufficient and robust evidence.
- 4.4. Responsible Science, i.e., adherence to the highest standards of research, from bench to bedside, in accordance with international and professional norms.
- 4.5. Respect for the subjects, i.e., The principle of respect for persons requires recognition of the personal dignity of all individuals, acknowledgment of the centrality of personal choice, and respect for individual decisions. All people have equal moral value, regardless of their genetic qualities.
- 4.6. Fairness i.e., like cases be treated alike, and that risks and benefits be equitably distributed.

5. Clinical trials using genome editing will be permitted only in the following circumstances:

- 5.1. The absence of reasonable alternatives to preventing a serious disease or condition.
- 5.2. If it is convincingly demonstrated that gene editing is the only available alternative.

5.4. If credible pre-clinical and/or clinical data on risks and potential health benefits of the procedures are available.

5.5. Oversight of the effects of the procedure on the health and safety of the research participants is required.

5.6. Comprehensive plans for long-term, multigenerational follow-up with respect for personal autonomy.

5.7. Maximum transparency consistent with patient privacy.

5.8. Continued reassessment of health and societal benefits and risks.

7. Application is Limited to Therapeutic Purposes Only

7.1. The extension to uses of gene editing technologies are limited only to prevent a serious disease or condition.

7.2. Heritable (Germline) Genome Editing prohibited as it could impact the offspring as well as future descendants of the individual receiving treatment.

9. Ensuring Transparency in Research Involving Gene Editing

9.1. Every Scientist/ Research Institution engaged in research/ clinical trial using gene editing technologies shall enter their names and the kind of research/ clinical trial they are conducting in the online portal of ACMR.

9.2. Every such entry in the online portal should specify the nature of research, the persons involved in the said research, objective of the research and the possible outcome of the said research.

IMPORTANT NOTE

*Ujjevan technology mentioned in the moot proposition is similar to the CRISPR-Cas9 technology, which is used as a genome-editing tool. The CRISPR-Cas9 has widespread applications in fields spanning model organisms, functional genomics, epigenetic screens, and human therapeutics.

1. This is a work of fiction. Names, characters, businesses, places, events and incidents are either the products of the author's imagination or used in a fictitious manner. Any resemblance to actual persons, living or dead, or actual events is purely coincidental.

2. The decisions of the organizers shall be final and ultimate.
