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Are we ready for Designer Babies

Strategic, Legal, Tax and
Ethical issues

October 2024

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**Strategic, Legal, Tax and Ethical
Issues**

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Acknowledgements

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*With genetic engineering, we will be able to increase the complexity of our DNA, and improve the human race. But it will be a slow process, because one will have to wait about 18 years to see the effect of changes to the genetic code – **Stephen Hawking***

*Transhumanism is the ethics and science of using things like biological and genetic engineering to transform our bodies and make us a more powerful species. – **Dan Brown***

*I don't think we are going to see superman or a split in the species any time soon, because we just don't know enough – **Henry Greely, bioethicist***

*I see nothing wrong ethically with the idea of correcting single gene defects through genetic engineering. But I am concerned about any other kind of intervention, for anything else would be an experiment, which would impose our will on future generations and take unreasonable chances with their welfare ... Thus, such intervention is beyond the scope of consideration. – **Ian Wilmut in The Second Creation: Dolly and the Age of Biological Control***

*Oh, happy day, when miracles take place
And scientists control the human race,
When we assume authority of human chromosomes,
And assembly-line women,
Conveyor-belt men
Settle down in push-button homes. – **Li'l Abner, "Oh, Happy Day"***

*How could you do something like that? That's horrible, going around altering the genetics of babies!
How could you do that to my parents? – **Children of an Elder God***

*The cloning of humans is on most of the lists of things to worry about from Science, along with behaviour control, genetic engineering, transplanted heads, computer poetry and the unrestrained growth of plastic flowers. – **Lewis Thomas***

*Genetic engineering has never been about saving the world, it's about controlling the world. – **Vandana Shiva***

*India has the opportunity to be a leader in genetic engineering, It has institutions that no other country has. – **Nina Fedoroff***

*It is difficult to imagine a greater imposition than adding genes to future generations that changes the nature of future people. – **Ian Wilmut***

*The time to talk about it [genetic engineering to improve a baby's genes] in schools and churches and magazines and debate societies is now. If you wait, five years from now the gene doctor will be hanging out the MAKE A SMARTER BABY sign down the street. – **Arthur Caplan***

I suspect any worries about genetic engineering may be unnecessary. Genetic mutations have always happened naturally, anyway. – James Lovelock

Genetic engineering is a result of science advancement, so I don't think that in itself is bad. If used wisely, genetics can be beneficial, but they can be abused, too. – Hideo Kojima

Right now people are interested in genetic engineering to help the human race. That's a noble cause, and that's where we should be heading. But once we get past that - once we understand what genetic diseases we can deal with - when we start thinking about the future, there's an opportunity to create some new life-forms. – Jack Horner

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Executive Summary

Genetic Engineering is poised to create a revolution that may lead to significant ethical and legal issues considering its impact on human lives and possibly value system. It is likely to make more severe impact, if it is practiced in India.

Genetic engineering or gene editing, in simple terms, is the direct manipulation of an organism's genes, to alter an organism's characteristics in a particular way. While this technology has been known to scientists for a long time, it is the rapid development of this technology, through germ line gene editing, more specifically through the CRISPR-Cas9 technique, which has taken over the world by storm. With the capacity to alter the genes of a human embryo, potentially removing all the genetic defects and introducing new characteristics, germ line gene editing is ushering in a brave new world. This brings to the focus the capability or in some cases, incapability of national and international law to regulate research into this unknown but welcome field. It definitely brings to light certain social, ethical and religious concerns surrounding genetic editing which could be passed from one generation to the other. The policies and guidelines framed by many countries with respect to gene editing are failing to keep up with the speed of advancement made in the field.

In this research paper, we have analyzed the legal and regulatory framework applicable to germ line gene editing, with specific emphasis on its application to produce designer babies. We have also analyzed some of the pressing ethical and social issues that surface in context of producing designer babies. A comparative analysis of the legal position on germ line gene editing adopted by USA, UK, China and Japan has also been undertaken. The paper concludes with legal recommendations for regulation of germ line gene editing in India.

Introduction

The Oxford Dictionary¹ defines “designer baby” as “a baby whose genetic makeup has been selected in order to eradicate a particular defect, or to ensure that a particular gene is present.”

A designer baby could, in theory, be free from genetic diseases such as haemophilia, cystic fibrosis or muscular dystrophy and many such diseases. The designer baby could also have traits and characteristics considered as preferred traits, such as height, eye color, musicality, intelligence etc.

While the idea of a designer baby has till now been a far-fetched dream, it appears that it could now become a reality. A scientist in China has reportedly already modified the germline of live fetuses to make them HIV-free by genetic design. The twin girls whose genes were modified have already taken birth and a third such baby is on the way.² A designer baby, therefore, may be a reality soon, made possible by human germline editing in India as well.

However, the definition of “designer baby” does not fully indicate the consequences of creating a designer baby and hence they need to be discussed and understood. Germline editing, used in the creation of designer babies, is a form of genetic modification that involves changing genes in eggs, sperm, or very early embryos. This type of genome modification is heritable, meaning that the modified genes could appear not only in the offspring that result from the procedure, but also in the subsequent generations.³ Heritable genome editing interventions are not currently available as a reproductive option, but they could be in the future. The aim of heritable genome editing would be to edit a sequence of Deoxyribonucleic acid (“DNA”) in an embryo, sperm, or egg, in order to replace a variant of a gene that has one kind of effect with another known variant that has a different effect (for example, to replace a disease-causing variant with a non-disease variant). The edited DNA would then become part of the genome of the growing embryo so that any future person resulting from that embryo, sperm, or egg would have that variant in all their cells.⁴ Therefore, it is not surprising that human germline modification has for many years been widely considered off-limits, for both safety and social reasons. It is formally prohibited in more than 40 countries.⁵

A. Important concepts

Before diving into the law and ethics behind germ line genetic editing (which could lead to creation of designer babies), it is important to understand some of the scientific terms frequently used in this research paper.

- a) **Gene:** A gene is the basic physical and functional unit of heredity that is present in all cells. Genes are made up of DNA.⁶

1 Oxford English Dictionary Twelfth Edition, 2011.

2 <https://www.technologyreview.com/s/612458/exclusive-chinese-scientists-are-creating-crispr-babies/>.

3 National Guidelines for Stem Cell Research 2017, Glossary.

4 Nuffield Council on Bio ethics, Genome editing and human reproduction: social and ethical issues short guide,; <http://nuffieldbioethics.org/wp-content/uploads/Genome-editing-and-human-reproduction-short-guide-website.pdf> (last accessed on Sep. 8, 2018).

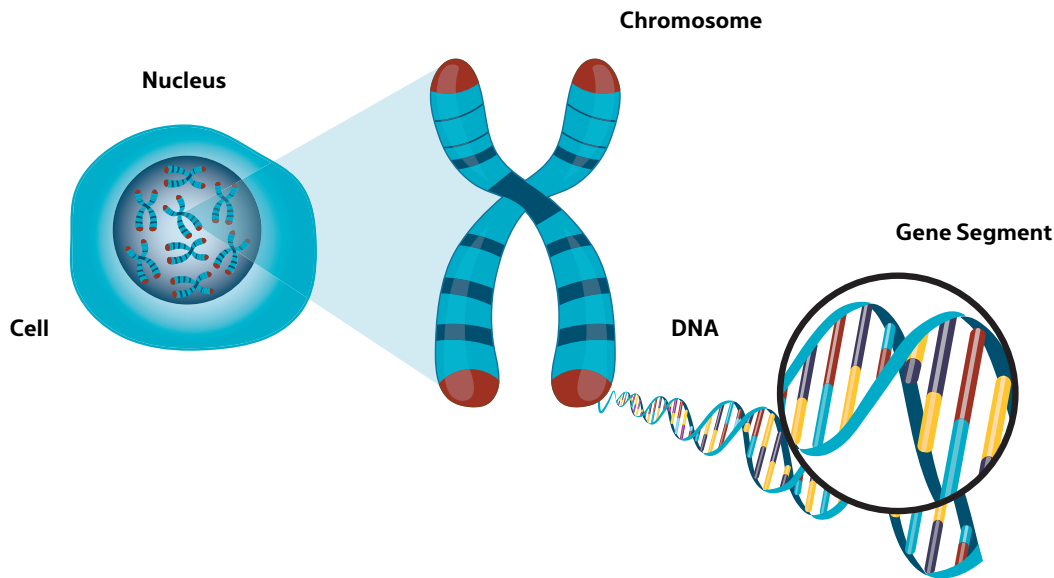
5 Center for Genetics and Society, About Human Germline Gene Editing,; <https://www.geneticsandsociety.org/internal-content/about-human-germline-gene-editing> (last accessed on Sep. 8, 2018).

6 <https://ghr.nlm.nih.gov/primer/basics/gene>.

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- b) **DNA:** DNA, or deoxyribonucleic acid, is a molecule that carries the hereditary material in humans and almost all other organisms. Over 99% of DNA is same in all people.⁷ The DNA in our genes contains the ‘code’ which is read by each and every cell of the body in order to understand its expression i.e. its role and function in the body. It is the code stored in our genes that define our physical makeup such as heights, skin or hair color and may also influence certain behavioral traits.

INSIDE THE CELL

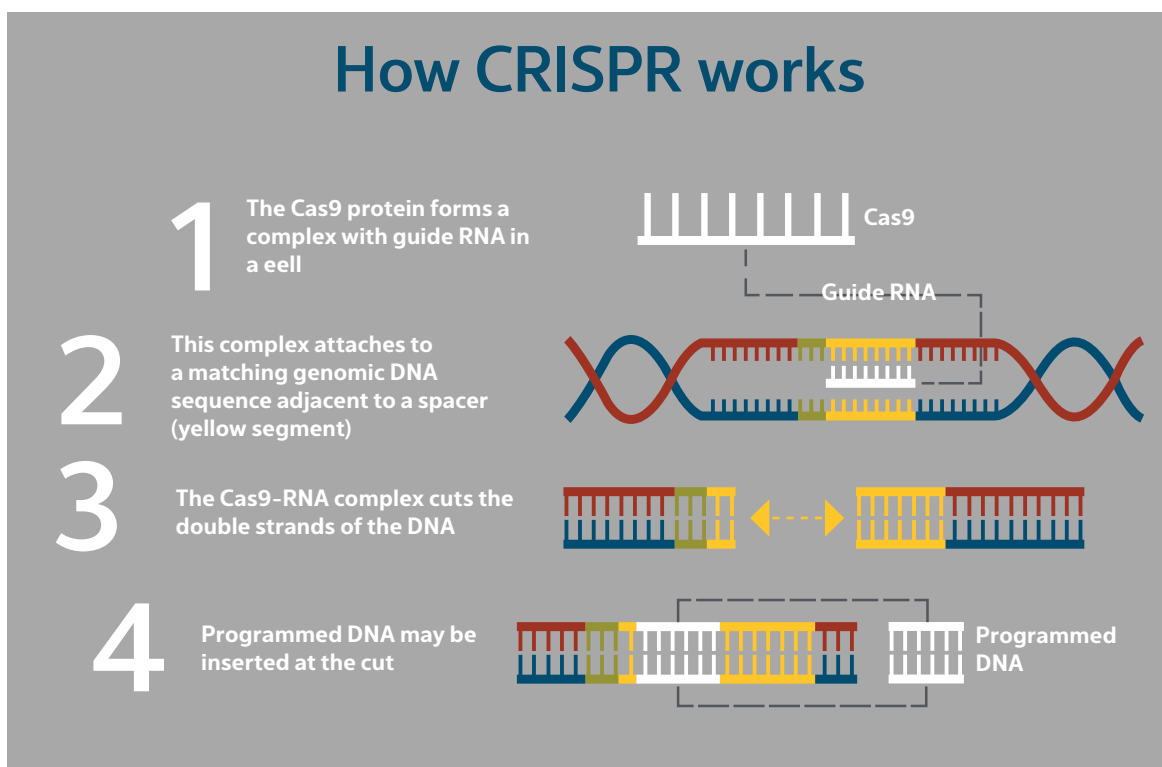


- c) **Gamete:** A mature male or female reproductive cell usually possessing a haploid set of chromosomes and capable of initiating formation of a new diploid individual by fusion with a gamete of the opposite sex i.e. an egg (in the female) and a sperm (in the male). A diploid set of chromosomes is double the haploid number of chromosomes in an organism. In humans, the diploid number of chromosomes is 46.
- d) **Germ cell:** Ova and sperm, and their precursors.
- e) **Embryo:** In humans, it is an early stage of development of a multicellular diploid eukaryotic organism from the time of fertilization of ova until the end of the eighth week of gestation, after which it is known as a fetus.
- f) **Fetus:** In humans, it is the developing stage of a multicellular diploid eukaryotic organism that follows the embryonic stage, i.e. from eight weeks post fertilization till birth
- g) **In vitro:** Of processes or reactions taking place in a test tube, culture dish, or elsewhere outside a living organism.
- h) **In vivo:** Of processes taking place in a living organism
- i) **Gene therapy:** A scientific technique for treatment or prevention of disease or disorder by insertion or removal of a gene.
- j) **‘Spare’ embryo:** An embryo created during the course of in vitro fertilization (“**IVF**”) treatment of the infertile couple which is not utilized for the purpose of IVF, also known as supernumerary embryo.

⁷ <https://ghr.nlm.nih.gov/primer/basics/dna>.

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- k) **CRISPR:** CRISPR stands for clustered, regularly interspaced, short palindromic repeats. Cas9 stands for CRISPR-associated protein 9 (Cas9). It is a revolutionary technique for germ line gene editing that has made gene editing cheaper and more accessible to scientists and laboratories.
- l) **CRISPR:** Cas9 technology allows scientist to cut-and-paste a desired 'code' in the gene. The specific location of the genetic code that is required to be altered is identified on the DNA strand, and then, using the Cas9 protein, which acts like a pair of scissors, that location is cut off from the strand. A DNA strand, when broken, has a natural tendency to repair itself. Scientists intervene during this auto-repair process, supplying the desired sequence of genetic codes that binds itself with the broken DNA strand.⁸



⁸ <http://www.insightsonindia.com/2018/11/28/crispr-technology/>.

Legal and Regulatory Framework with Analysis

The legal framework in various jurisdictions is diverse, taking into consideration the vast differences in social, cultural and moral norms. It is nonetheless important to see the legal and regulatory framework in India and other jurisdictions to understand the law and how these countries have treated the germ line gene editing-

A. India

India does not have any specific law that explicitly prohibits genetic editing of germ lines. However, the Indian Council of Medical Research (“ICMR”), a government organization, published the National Ethical Guidelines for Biomedical and Health Research on Human Participants (“**Ethical Guidelines**”), which prohibited “*eugenic genetic engineering for changing/selecting/altering genetic characteristics and creating so called designer babies...*” In addition to the Ethical Guidelines, the National Guidelines for Stem Cell Research 2017 (“**Guidelines**”) published by the ICMR and the Department of Biotechnology, Ministry of Science & Technology (“**DBT**”), provide all the necessary guidance for cellular research including gene editing or modification, human germ-line engineering and reproductive cloning.

The Guidelines prohibit research related to human germ line gene therapy in the current state of scientific knowledge and understanding. Research involving implantation of human embryos (generated by any means) after in vitro manipulation, at any stage of development, into uterus in humans or primates is also strictly prohibited.¹

To the extent that genome modification is permitted, such modification can only be done through in vitro studies (i.e. outside the human body) and requires thorough review by the Institutional Committee for Stem Cell Research (“**IC-SCR**”), the Institutional Ethics Committee (“**IEC**”), and the Institutional Biosafety Committee (“**IBSC**”), and the Review Committee on Genetic Manipulation (“**RCGM**”). In-vitro studies can only be conducted on spare embryos, germ-line cells or gametes. Further, the genome modified human embryos should not be cultured beyond 14 days of fertilization or formation of the primitive streak, whichever is earlier to ensure that these embryos should not have a possibility of being inserted into the womb.²

Therefore, any research that may lead to creation of designer babies is prohibited by non-mandatory guidelines in India.

B. USA

In the USA, the acceptance of the use of germ line editing has been growing slowly but steadily. The National Institute of Health (“**NIH**”), which is a part of the U.S. Department of Health and Human Services, published guidelines the, “**NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules**” in 2016 which stated that the NIH would not entertain proposals for germ line alterations,

¹ Clause 8.3 Prohibited Areas of Research of Guidelines.

² Clause 8.2. Restrictive Areas of Research of Guidelines.

involving a specific attempt to introduce genetic changes into the reproductive cells of an individual, with the aim of changing the set of genes passed on to the individual's offspring. It did however state that it would consider proposals involving somatic cell gene transfer.³

In 2017 however, the National Academy of Science (“NAS”), a private not-for-profit organization which provides advice to the US Government on matters of science and technology, published a report titled, “**Human Genome Editing Science, Ethics and Governance**” (“**Report**”) which states that given both the technical and societal concerns, there is a need for caution in any move towards germ line editing. However, that caution does not mean prohibition. The Report gave a cautious green light to germ-line editing under certain conditions which include:⁴

- i. absence of reasonable alternatives;
- ii. restriction to preventing a serious disease or condition;
- iii. restriction to editing genes that have been convincingly demonstrated to cause or strongly predispose to that disease or condition;
- iv. restriction to converting such genes to versions that are prevalent in the population and are known to be associated with ordinary health with little or no evidence of adverse effects;
- v. availability of credible pre-clinical and/or clinical data on risks and potential health benefits of the procedures;
- vi. during the trial, ongoing, rigorous oversight of the effects of the procedure on the health and safety of the research participants;
- vii. comprehensive plans for long-term multigenerational follow-up that still respect personal autonomy;
- viii. maximum transparency consistent with patient privacy;
- ix. continued reassessment of both health and societal benefits and risks, with broad, ongoing participation and input from the public; and
- x. reliable oversight mechanisms to prevent extension to uses other than preventing a serious disease or condition.

The Report recommends that germ line editing research trials might be permitted but should only be done for compelling reasons of treating or preventing serious disease or disabilities and under strict oversight. The committee also recommended that genome editing for purposes other than treatment or prevention of disease and disability (for example enhancement) should not be conducted, and that it is essential for public discussions to precede any decisions about whether or how to pursue clinical trials of such applications.

On the heels of the conditional green light given by the NAS, the researchers in Portland, Oregon undertook the gene editing of human embryos, which is explained below.

3 NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules see Appendix M.

4 NAS, Human Genome Editing Science, Ethics and Governance: http://nationalacademies.org/cs/groups/genesite/documents/webpage/gene_177260.pdf (last accessed on Sep. 8, 2018).

C. UK

The UK has in recent times, been liberal towards allowing gene editing after fulfillment of certain conditions. The Human fertilization and Embryology Act 1990 (“**HFEA**”) regulates the law on research on embryos. The HFEA permits research projects on embryos with a license, provided the embryo is not kept for a period of more than 14 days and not transferred into the womb of a woman.⁵ In 2015 the Human fertilization and Embryology (Mitochondrial Donation) Regulations were passed which allowed for germ-line modification of nuclear DNA that could be passed on to future generations. However, the government was firm in its distinction between mitochondrial donation and genetic modification, stating that mitochondrial donation does not affect any genes transmitted through germ line of men born through these techniques, but accepted that it could still be defined as germ line therapy.⁶

The UK’s approach to germ line gene editing has been more open than rest of the world. It is lawful in the UK to create and use genome edited human embryos, sperm or eggs in research, under strict licensing conditions. However, it is still illegal to use gene edited human embryos in assisted reproduction.⁷ The authority constituted under HFEA, the Human fertilization and Embryology Authority granted a license in 2016 to scientists in London to alter genes that are active in healthy human embryos in the first few days after fertilization. The researchers could do the experiments only for seven days, after which the embryos were to be destroyed. The genetic modifications could help researchers to develop treatments for infertility, but will not themselves form the basis of a therapy. This approval represents the world’s first research project on genetic editing endorsed by a national regulatory authority.⁸

The development of acceptance of gene editing in UK has been progressing impressively. In July 2018, the Nuffield Council on Bioethics, the ethics body of the U.K., published a report titled “**Genome editing and human reproduction: social and ethical issues**”, and concluded that the use of genome editing interventions to influence the characteristics of future generations could be ethically acceptable in some circumstances, provided it upholds the principals of social justice and solidarity, i.e. it should not be expected to increase disadvantage, discrimination, or division in society. It also laid down that the welfare of the future person, who may be born as a consequence of such genetic editing procedures, is kept supreme.

Therefore, it is seen the UK laws are more expansive and inclusive to allow for research into “designer babies.”

D. China

In China, there is no legislation regulating genome editing or engineering of human embryos. However, guidelines called the “**Ethical Principles and Conduct Norms of Human Assisted Reproductive Technologies**” (“**HAP Guidelines**”) prepared in 2001, by the Ministry of Health of the People’s Republic of China lay down certain ethical principles for human assisted reproductive technologies as well as guidelines for practitioners.

⁵ Schedule 2 of HFEA.

⁶ Department of Health, In Vitro Fertilisation: Written question - HL4366: <https://www.parliament.uk/business/publications/written-questions-answers-statements/written-question/Lords/2015-01-22/HL4366/> (last accessed on Sep. 8, 2018).

⁷ Supra note 4, at 3.

⁸ Ewen Callaway, UK scientists gain licence to edit genes in human embryos: <https://www.nature.com/news/uk-scientists-gain-licence-to-edit-genes-in-human-embryos-1.19270> (last accessed on Sep. 8, 2018).

The HAP Guidelines prohibit the manipulation of the gene in human gamete, zygote or embryo for the purpose of reproduction.⁹ Therefore, the prohibition in gene manipulation is limited to reproduction and does not extend to research. Experiments conducted for research purposes using embryos which will never develop into humans are outside the scope of the guidelines and are therefore, permitted. Taking advantage of this loophole, Chinese scientists have reportedly conducted gene editing experiments, which are explained in the next section.

E. Japan

Japan at present, does not have a legal framework specific to genome editing. However, in response to the experiments conducted in China in 2015, the Japanese Cabinet Office's Life Ethics Study Group ("**LESG**") issued an interim report in April 2016 accepting basic genome editing research on manipulating genes in fertilized human embryos but regarded the returning of embryo whose problematic gene was modified through genome editing to a womb as unacceptable.¹⁰ The LESG report laid down that such research on genome editing may be conducted for purposes relating to embryonic development; treating congenital hard-to-cure diseases and improving assisted reproductive technologies. The report, however cautioned the researchers to limit the research to 14 days of a human embryo's development and to dispose of the embryos after research is conducted. The LESG flatly turned down clinical use of human genome editing at this stage, citing the following risks-

- i. Inaccurate or incomplete editing such as off-target mutations and mosaicism;
- ii. Interminglement of modified and unmodified genes;
- iii. Difficulty to predict what effects gene alteration; and
- iv. Risks that future generations may face as a result of genetic alterations in embryos passed from generation to generation.¹¹

Apart from the LESG report, Japan has no law governing research into or clinical use of genome editing.

F. Other Important Jurisdictions

In Canada, human germline editing is banned. It is criminalized under the 2004 Assisted Human Reproduction Act ("**AHRA**"), and punishable by fines of 500,000 Canadian dollars and the possibility of punishable with fine. AHRA however, lacks a clear regulatory body to oversee its implementation.¹²

9 Unofficial translation of the Ethical Principles and Conduct Norms of Human Assisted Reproductive Technologies.": <https://mrc.ukri.org/publications/browse/china-uk-research-ethics-cure-committee-report/> see page 46.

10 <http://www.eubios.info/EJAIB112016.pdf> (last accessed February 6, 2019).

11 Japan Times, Human genome editing.: https://www.japantimes.co.jp/opinion/2016/09/26/editorials/human-genome-editing/#article_history (last accessed on Sep. 7 2018).

12 Kathleen M. Vogel, Crispr goes global: A snapshot of rules, policies, and attitudes: <https://thebulletin.org/2018/06/crispr-goes-global-a-snapshot-of-rules-policies-and-attitudes/> (last accessed on Sep. 8, 2018).

Recent Medical And Technological Advances

In November 2018, it was reported that a scientist in China had been carrying out genetic tests out on fetuses as late as 24 weeks, and that the world's first genetically edited babies using CRISPR-Cas9 technique, a set of twin girls, have already been born. As a result, the unofficial international moratorium on editing human embryos intended for a pregnancy had been violated. The scientist in question, has defended his decision to edit genes of the baby girls stating that the objective of his experiment was to disable a gene called CCR5 so the girls might be resistant to potential infection with HIV/AIDS. This was important because the father of the girls had HIV and wanted to ensure his children would never suffer like he has.¹

Some other notable advances are listed below:

- i. Chinese scientists at Sun Yat-sen University in Guangzhou attempted to modify the gene which is responsible for β -thalassaemia, a potentially fatal blood disorder, using CRISPR-Cas9. During the experiment, 54 embryos which could not result in a live birth (nonviable) were genetically tested. Out of the 54 embryos tested only 28 were successfully spliced, and that only a fraction of those contained the replacement genetic material. While the rates of “off-target” mutations were much higher than those observed in gene-editing studies of mouse embryos or human adult cells,² this experiment illustrates the medical strides that have been taken by the scientists in attempting to not only eradicate genetic disease in embryos, but also take positive action towards creating a genetically modified child, who may be completely illness free.
- ii. The potential of gene editing to cure diseases and save lives is evidenced by a recent report of a baby having incurable leukemia getting highly experimental, genetically edited cells in a tiny 1-milliliter intravenous infusion.³ This treatment used ‘molecular scissors’ to edit genes and create designer immune cells programmed to hunt and kill drug resistant leukaemia. This breakthrough came from Great Ormond Street Hospital (“GOSH”) and University College London’s Institute of Child Health’s (“ICH”) pioneering research teams with support from the National Institute for Health Research (NIHR) Great Ormond Street Biomedical Research Centre.⁴
- iii. In USA, a team of researchers in Portland, Oregon attempted at creating genetically modified human embryos, by changing the DNA of a large number of one-cell embryos with the use of gene-editing technique CRISPR. None of the embryos were allowed to develop for more than a few days, but CRISPR was injected into the eggs at the same time they were fertilized with sperm in order to avoid the “off target” effect that was found in the Chinese experiments.⁵
- iv. In India, there has been no reported germ line gene editing experiment on human embryos. This is a marked difference to China, USA and UK, where there have huge leaps forward towards development of this field.

1 <https://www.vox.com/science-and-health/2018/11/30/18119589/crispr-technology-he-jiankuil>; <https://www.nytimes.com/2018/11/26/health/gene-editing-babies-china.html>; <https://www.technologyreview.com/s/612458/exclusive-chinese-scientists-are-creating-crispr-babies/>.

2 David Cyranoski and Sara Reardon, Chinese scientists genetically modify human embryos: https://www.nature.com/news/chinese-scientists-genetically-modify-human-embryos-1.17378?WT.mc_id=TWT_NatureNews (last accessed on Sep. 8, 2018).

3 Kate Kelland, Baby With Incurable Leukemia Cured With Designer Immune Cells: https://www.huffingtonpost.com/entry/baby-with-incurable-leukemia-cured-with-designer-immune-cells_us_563bf870e4b0411d3070759a (last accessed on Sep. 8, 2018).

4 GOSH, World first use of gene-edited immune cells to treat ‘incurable’ leukaemia: <https://www.gosh.nhs.uk/news/latest-press-releases/2015-press-release-archive/world-first-use-gene-edited-immune-cells-treat-incurable-leukaemia> (last accessed on Sep. 8, 2018).

5 Steve Connor, First Human Embryos Edited in U.S.: <https://www.technologyreview.com/s/608350/first-human-embryos-edited-in-us/?set=608342> (last accessed on Sep. 8, 2018).

Ethical Issues

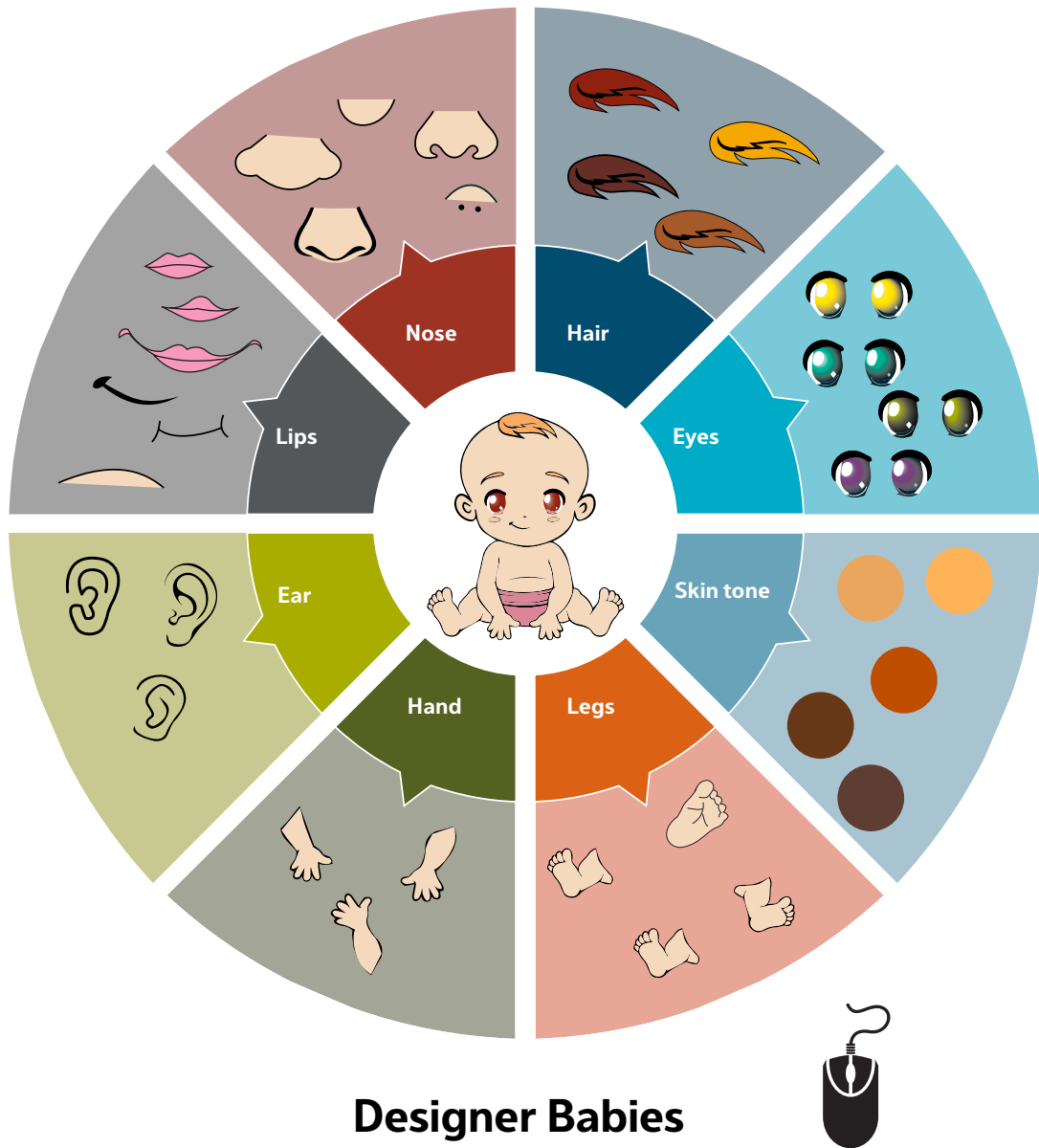
More than legal restrictions, it is the ethical and social concerns surrounding creation of designer babies that act as a major roadblock for the science. Some of these concerns are enumerated below:

- i. There is fear that permitting germ line gene editing would lead to the creation of offspring having some preferred traits. Parents who want specific traits in their children such as a specific hair or eye color, height, memory, intelligence, would opt for such genetic modification in order to get the desired baby. This may lead to a division in society where genetically modified humans are healthier and conform better to societal standards of beauty than non-genetically modified humans. Germ line gene editing can also make upward social and economic mobility for persons from disadvantaged communities more difficult as such persons will not have been genetically modified to be more intelligent and attractive as compared to their richer peers. Another issue with germ line gene editing is a possible widening of the health gap between rich and poor, both within a society and between nations.¹
- ii. A distinction must be made between treating a person that already exists versus genetically modifying an embryo.² Modifying the genetic make-up of an already existing person is more likely to be seen as treatment, especially in cases where such individual is unlikely to reproduce. Any genetic changes in the individual will come to an end with the death of such individual.
- iii. Another concern that has been raised by many scientists is that since genome editing in human embryos could have unpredictable effects on future generations, especially if such research is exploited for non-therapeutic modifications. Unexpected genetic mutations are often introduced in the genome when the CRISPR-Cas9 technique is applied and these mutations can be passed from one generation to the other. Concerns about adverse irreversible changes in the human gene pool are valid. However, such concerns may also hinder any efforts made towards developing therapies that use gene editing technology for changes that cannot be inherited, such as developing a cure for cancer.
- iv. Legalization of designer babies also raises questions with respect to the degree of parental intervention acceptable when changing the appearance of the fetus. Currently, parents exert limited control over the appearance and personality of their child. A child's personality is impacted not only by her home environment but also through her lived experiences outside the home. Allowing parents to pick traits for their child before such child is born diminishes the influence of other factors. For instance, behavioral traits such as obedience, laziness or a tendency to procrastinate are partially inherited and partially learnt. Through gene editing, parents can ensure that their child is obedient and less likely to question authority thereby eliminating the nurture portion of nature versus nurture. Some parents may focus more on making sure their child is beautiful while others may choose to make their child more intelligent or more musical. Parents can even make sure their child has a small appetite. In either case, the child has no control over the traits it will ultimately possess. For the child the degree of their intelligence or attractiveness is decided either by fate or by their parents. Neither is objectively fairer than the other. Additionally, as discussed above, parents do exert a good deal of influence on their children in status quo. Parents make decisions with respect to what city the child will be brought up in, what school the child will attend, who the child interacts with when growing up, and even what the child eats. Allowing parents to pick physical or character traits is not much of a leap from letting parents pick their child's name, an indicator of her identity for her entire life.

1 Philip Ball, Designer babies: an ethical horror waiting to happen?: <https://www.theguardian.com/science/2017/jan/08/designer-babies-ethical-horror-waiting-to-happen> (last accessed on Sep. 8, 2018).

2 Supra note 4, at 3.

Gene editing fetuses could also lead to an interesting set of lawsuits. In 2014, a court in England held that the mother of a child born with fetal alcohol spectrum syndrome due the mother’s heavy drinking during pregnancy is not guilty of causing harm to the child. If designer babies become a reality, we may see many more lawsuits with children suing their parents for the decisions made when the child was in the womb.



Intellectual Property Right Issue

The potential creation of a designer baby brings forth a multitude of intellectual property right issues. The first issue is whether a human gene is patentable. A gene patent is the exclusive rights to a specific sequence of DNA (a gene) given by a government to the individual, organization, or corporation who claims to have first identified the gene. Once granted a gene patent, the holder of the patent dictates how the gene can be used, in both commercial settings, such as clinical genetic testing, and in noncommercial settings, including research.¹

The Supreme Court of the US (“SCOTUS”) has laid down that human genes cannot be the subject matter of a patent. In *Association for Molecular Pathology v. Myriad Genetics*² SCOTUS was required to decide whether a naturally occurring segment of DNA- gene, by its isolation from rest of the human genome is patentable. This would grant an exclusive right to the patentee (Myriad) to further study, manipulate or use that particular gene. The Court held that the location and order of the gene existed in nature before the patentee discovered the gene. Therefore, the patentee did not alter or create the genetic structure. The only contribution was uncovering the precise location and genetic sequence of the gene in question. The court emphatically laid down that nothing new is created when discovering a gene, as it is a product of nature. Consequently, there is no intellectual property to protect through a grant of patent. A human gene is not eligible for a patent merely because it has been isolated. The Court distinguished DNA that naturally occurs in humans from DNA, which is manipulated in a laboratory, like synthetic DNA (complementary DNA). Synthetic DNA can be patented because it is not naturally occurring. The Court further explicitly refused to pass judgement on scientific alteration of the genetic code.

The European Union, in Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (“Directive”), provides that the mere discovery of a sequence or partial sequence of a human gene cannot be patented. However, an element isolated from the human body or produced by means of a technical process, including the sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.³ Thus, isolation of gene is patentable in Europe, where as in the USA it is not. Further, the European Union, under the Directive explicitly prohibits the patentability of processes for modifying the germ line genetic identity of human as well as the use of human embryos for industrial or commercial purposes.⁴ This was implemented, in particular, to respect the physical integrity of descendants.⁵ This provision gives concrete form to the concepts of *ordre public and morality*.⁶

In India, to be patentable, a product or a process must be novel, involve an inventive step and be capable of industrial application.⁷ Discovery⁸ by itself will not merit a patent. Therefore, mere discovery of a gene which is naturally occurring in nature will not amount to an invention and is not patentable.

1 Genetics Home Reference, Can genes be patented?, available at: <https://ghr.nlm.nih.gov/primer/testing/genepatents> (last accessed on Jan. 23, 2019).

2 Association for Molecular Pathology v. Myriad Genetics 569 U.S. 576 (2013).

3 Article 5 of Directive.

4 Rule 23d of European Patent Convention Regulations; Dr. Franz Zimmer, New Rules of the European Patent Office for Biotechnological Inventions,; <https://gruenecker.de/fileadmin/Gruenecker/Informationen/Veroeffentlichungen/biorules.pdf> (last accessed on Jan. 19, 2019).

5 Report from the Commission to the European Parliament and the Council - Development and implications of patent law in the field of biotechnology and genetic engineering,; <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52002DC0545:EN:HTML>.

6 Supra note 38, at 17.

7 Section 2(1)(j) of PA.

8 Section 3 (c) of PA.

Further, the Guidelines for Examination of Biotechnology Applications for Patent, 2013 (“GEBAP”) state that sequences isolated directly from nature are not patentable.⁹

While genes or sequences naturally occurring in nature are not patentable, a human gene sufficiently altered or modified, showing a degree of inventive advancement, non-obvious to a person skilled in the art, as well as capable of industrial application may merit a product patent. It is vital to remember that under the Guidelines, as explained previously, genome modification is restricted only to in vitro studies and a genome modified human embryo cannot be cultured beyond 14 days of fertilization or formation of primitive streak, whichever is earlier, thus eliminating all scope for the commercial or industrial use of such modified gene. As a result, even if altering a gene fulfils the criteria for novelty, inventive step and industrial application, it will still be ineligible for a product patent in view of the restriction given under the Guidelines prohibiting the use of such gene after 14 days.

Further, an invention the primary or intended use or commercial exploitation of which could be contrary public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment is also not patentable.¹⁰ Under the premise that the germline gene modification is unethical and may lead to moral disturbances in the public sphere, it may not be accepted as an invention and therefore, not be patentable.

9 Part 11 of GEBAP.

10 Section 3(b) of PA.

Limitations and Challenges in India

In India, the limitations to creating a designer baby are many fold, the Guidelines being the primary obstacle. The Guidelines prohibit even research into human germ-line gene therapy. It further categorically prohibits research involving implantation of human embryos (generated by any means) after in vitro manipulation, at any stage of development, into uterus in humans. However, the million dollar question to be answered is whether the guidelines have the force of law?

While the Guidelines have not been issued under any law or have been ratified by India's legislature, they are still sanctions attached to disobeying the Guidelines.

Medical practitioners are governed by a code of conduct. In India, the code of conduct applicable to registered medical practitioners is called Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002 (**"MCI Code"**). The MCI Code provides that research involving patients or volunteers can be undertaken, provided ethical considerations are borne in mind. Violation of existing ICMR guidelines (such as the Guidelines) amounts to professional misconduct.¹ If the medical practitioner is found to be guilty of committing professional misconduct, then the name of such practitioner may be removed from the register maintained by the Medical Council of India and/or State Medical Councils,² meaning that such medical practitioner will not be able to practice medicine in India. Since non-compliance with the Guidelines is deemed to be unethical; it is quite likely that doctors involved in any research involving genetic editing for creation of designer babies may lose his/her license to practice.

Therefore, the Guidelines may be enforced indirectly through other legal instruments that apply to professionals, such as the MCI Code.

Moreover, the Delhi High Court in the case of *Roche Products India Pvt Ltd v Drugs Controller General of India*³ made an important observation with respect to binding nature of guidelines issued by governmental agencies stating that

"54. As regard binding nature of the guidelines, it is well settled principle of law that the guidelines are in the nature of the directions issued by the government and till the time the said guidelines and directions are not in contradiction but are mere addition to the already existing rules and regulations, it cannot be said that the said guidelines are not having legal validity and are not required to be adhered to being non binding in character.

58....it is clear that the administrative orders, directions or guidelines do not create any justiciable right is a rule not without exception and in the cases where the guidelines are framed with aim to fill the gaps in the legal framework or regulatory measures or are supplemental rules, the courts can proceed to enforce them in the form of legally justiciable right in such circumstances."

1 Clause 7.22 of CMER.

2 Clause 8.2 of CMER.

3 2016 (66) PTC349 (Del).

Limitations and Challenges in India

In our assessment, the Guidelines do not have the force of law because there is no direct penalty associated with breach of the Guidelines. If, however, a professional association is of the opinion that it is unethical to intentionally breach the Guidelines, and that such breach amounts to professional misconduct of a degree that action should be taken against erring individuals, then the Guidelines may find force through a coercive order of the professional association. The observation of the Hon'ble High Court quoted above were issued in context of a guideline that was to enforce an existing law. Therefore, the observation should not be read in isolation.

The Present and Future of Designer Babies in India – A Clarion Call for Change

At the moment, it is clear that any research effort put towards creation of Designer Babies in India would be considered unethical on account of ICMR Guidelines. It is not, however, illegal because the ICMR Guidelines are not backed by a legislation. Having said that, while the enforceability of ICMR Guidelines can be questioned, the position of the Indian Government on Designer Babies cannot be. The ICMR guidelines make it very clear - India does not support creation of Designer Babies, period.

It has been famously said that science has the potential to change humanity, if humanity wishes to be changed. These words apply squarely to the science of germ line gene editing. The criticisms against creation of designer babies are not so much against the science itself, as they are against our inability to resist our urge to misuse the science.

We believe that the science presents real opportunities to push human race on the whole towards a disease free and healthier tomorrow. The science is not meant to regulate humans, for that we have the instrument of law for that. Therefore, India should work towards a legislation that regulates research into, and application of the research for creation of Designer Babies.

Designing the Law on Designer Babies

A blue-print of the proposed legislation in India:

- 1) To begin with, the legislation can control the laboratories where such research can take place. The legislation can specify that research on germ line gene editing with the intention of creating designer babies must only take place in laboratories controlled by the government, or laboratories that have supervision of a government appointed ethics committee. That way, the government will be able to check unethical application of the science.
- 2) The application of the science to humans i.e. implanting a fetus with edited germline so that it can grow into a healthier baby, may be regulated by requiring approval of a central body appointed by the government before such an implant can take place. This body can have representation from the scientific community, the society, NGOs and the government itself.
- 3) A central registry can be maintained by researchers who are working on the science. The registry should be regularly updated with the information of the scientific community at large to know what research is on-going and what are the results of such research.
- 4) Any research or its application outside the purview of legislation can be made a cognizable, non-bailable criminal offence, treating such experiment on lines of harm done to the body of a human being.

We hope that such a legislation based on the above blue print takes birth and sees the light of the day, before the science behind it dies a lonely death.

Conclusion

“Genetic engineering is a result of science advancement, so I don’t think that in itself is bad. If used wisely, genetics can be beneficial, but they can be abused, too. – Hideo Kojima”

It is very clear that there is tremendous potential to germline gene editing and its application in improving the human race. At the same time, it is also very clear that it is a very sensitive subject and needs to be approached with caution.

Like with any major technological break-through, the technology and its application is bound to be doubted. The biggest opposition to the technology, which can crudely be summarized as “playing god”, appears to be a perception issue which can be overcome by showcasing positive results. The benefits of science have always been doubted at early stages, and genetic engineering appears to be no exception. Unfortunately, the often quoted ‘dice’ appears to be loaded against the science. The use of the technique in China on fetuses without supervision has brought negative media coverage and cast doubts on funding/support of ethical and controlled experiments. If this science is not allowed to live, it will die an untimely death. A science that can in fact make difference of life and death, deserves more than a second chance.

We strongly believe that the science of germline gene editing will be the key that will unlock a more glorious future for the human race. In India, at least, the present circumstances are not conducive for germline gene editing, but the same could change with some innovative legal and policy ‘designing’.

Our expertise in Pharmaceutical and Healthcare

A. Introduction

At Nishith Desai Associates (NDA), Dr. Milind Antani, a successful surgeon turned lawyer leads the team that has represented various Pharma and Healthcare companies on regulatory issues as well as on transactions that have included PE and VC investments, M&A, Joint Ventures, Co-development, Multi-level collaborations and IP driven deals. The team has advised many companies on regulatory compliances allied to licensing and approvals, clinical trials, product promotions, advertisements, anti-corruption practices, ethical issues, MCI ethical guidelines, pricing related issues, FDI related concerns etc.

NDA's ongoing endeavors in conducting and facilitating original research in emerging areas of law, especially when it comes to Pharma and Healthcare, has helped our team to develop unparalleled proficiency to anticipate legal obstacles, mitigate potential risks and identify new opportunities for our clients on a global scale. Simply put, for conglomerates looking to conduct business in the subcontinent, NDA takes the uncertainty out of new frontiers.

Supported by a team of legal experts with unparalleled domain knowledge, the team brings with it not just legal proficiency but an acute understanding of the economics of the business led by key industry insights substantiated by his vast experience in the field.

However, the most important benchmark to us for our services will always be client satisfaction. Ranked at the coveted No.1 spot for 'Client Satisfaction' by RSG – Financial Times' in 2016, here is a glimpse into what our clients have to say about us:

- “We are very happy with their work and the solutions they provide. They are very quick, very accurate and very solutions-driven.”
- “They are responsive, reliable and seem to be well connected. We are comfortable with their advice and I would recommend them.”
- Clients enthuse: “He (Dr.Antani) is fantastic. He has specialized knowledge and understands the techniques and science behind our products. It's easy to get advice from him without having to explain the science.”

B. Services

I. Strategy

Our team holds forth on proving expert opinion to business entities in the pharmaceutical and healthcare at every phase of their growth cycle, including - formation, early stage financing, technology and licensing, research and development, intellectual property portfolios, initial public offerings and follow-on securities offerings, protection and litigation of intellectual property, development and financing of manufacturing facilities as well tax structuring.

The firm is especially well-equipped to service the legal and tax complexities attendant to multinational clients setting up operations in India. The firm also represents life science and healthcare clients across a wide range of services including the drafting and negotiation of research and collaboration agreements, intellectual property protection and litigation and numerous public finance, Joint Venture, M&A, private equity and venture capital transactions.

II. Regulatory Issues

We advise on various regulatory issues and compliances related to promotion, marketing, advertisement, pricing, HCP interaction, labelling, clinical trials, research and development, manufacturing, import & distribution. We also counsel pharmaceutical and healthcare companies on regulations related to collaborative activities in India such as joint ventures and partnerships.

III. Documentation and Advisory Services

The team's expertise is well established when it comes to providing strategic guidance on structuring, drafting and negotiation of various contracts including contract manufacturing agreements, contract research, service agreements, marketing and distribution agreements, outsourcing agreements, IP assignment and license agreements. Clinical trial agreements, master service agreement, nondisclosure agreement, sponsored research agreement, material transfer agreement and confidentiality disclosure agreements, informed consent forms and other relevant documents.

IV. Investments

Our knowledge and proficiency, when it comes to the pharmaceutical industry in India as well as globally, has been the main stimulus in the growth of our funds and private equity practice. We guide overseas private equity investors and venture capital funds on their investments in the pharmaceutical and healthcare industry through Term sheet, Due Diligence, Documentation and Negotiations.

V. Corporate Transactions

Our team provides advice and assistance across various corporate transactions, including Mergers & Acquisitions, Joint Ventures and various collaborations related to the licensing for drug developments in the pharmaceutical, biotechnology and healthcare sectors.

VI. IP Advisory

We assist in the drafting, filing and prosecution of intellectual property applications. We routinely handle the drafting of complex patent specifications for a wide array of technologies in addition to filing domestic,

PCT and National Phase patent applications and assisting in the filing of foreign patent applications and freedom to operate opinions. We assist clients in identifying their intellectual property in order to formulate comprehensive strategies to help clients protect and leverage such intellectual property. We also assist companies managing patent compliance, patent landscape study as well as trademark portfolio management with uniquely designed software. Our life science team also assists clients in conducting detailed IP audit of the portfolio of a company.

VII. Patent Litigation

We have an extensive litigation practice that focuses on the protection of patents and other intellectual property. As mentioned earlier, the presence of a surgeon, chemical and biomedical engineers, Indian patent agents and a U.S. Patent Attorney helps us to understand the underlying science and technology at great speed and provide focused solutions.

VIII. Funds

Our funds team is well equipped with the expertise of structuring and positioning life sciences funds in India. We guide our clients in order to maximize investment decisions in addition to servicing them in all aspects of tax and legal issues that arise when delving into venture investments in India.

IX. Due Diligence

We are able to undertake comprehensive legal and regulatory due-diligence of pharmaceutical and healthcare businesses with the help of our industry insights. Our expertise in the pharma and life sciences sector enables us to identify critical issues that a financial or strategic investor in pharmaceutical and healthcare companies should carefully understand and address.

X. Structuring

We routinely advice on structuring transactions from a tax, legal and regulatory perspective. On the tax structuring side, we advise and determine tax favorable jurisdictions for investment purposes, permanent establishment, and transfer pricing instruments. We also facilitate the establishment of business in India, including the incorporation of companies and logistical operations of setting up branches and liaison offices in India. We have and continue to advise several new life sciences clients on their India-related operational activities.

XI. Litigation

Our team assists and advices on pre-litigation strategies with respect to the current IP and regulatory landscape in India.

We have represented international and domestic clients in IP litigation and alternate dispute resolution. We have extensive experience representing clients at every level of the judicial system and virtually all disputes, from relatively simple matters to highly complex cases in product liability, patent infringement, antitrust and securities.

XII. Training

We conduct workshops for employees of pharma and healthcare companies on Indian legal and regulatory compliance requirements encapsulating the current pharma, life sciences and IP landscape at national and international seminars.

About NDA

At Nishith Desai Associates, we have earned the reputation of being Asia's most Innovative Law Firm — and the go-to specialists for companies around the world, looking to conduct businesses in India and for Indian companies considering business expansion abroad. In fact, we have conceptualized and created a state-of-the-art Blue Sky Thinking and Research Campus, Imaginarium Aligunjan, an international institution dedicated to designing a premeditated future with an embedded strategic foresight capability.

We are a research and strategy driven international firm with offices in Mumbai, Palo Alto (Silicon Valley), Bengaluru, Singapore, New Delhi, Munich, and New York. Our team comprises of specialists who provide strategic advice on legal, regulatory, and tax related matters in an integrated manner basis key insights carefully culled from the allied industries.

As an active participant in shaping India's regulatory environment, we at NDA, have the expertise and more importantly — the VISION — to navigate its complexities. Our ongoing endeavors in conducting and facilitating original research in emerging areas of law has helped us develop unparalleled proficiency to anticipate legal obstacles, mitigate potential risks and identify new opportunities for our clients on a global scale. Simply put, for conglomerates looking to conduct business in the subcontinent, NDA takes the uncertainty out of new frontiers.

As a firm of doyens, we pride ourselves in working with select clients within select verticals on complex matters. Our forte lies in providing innovative and strategic advice in futuristic areas of law such as those relating to Blockchain and virtual currencies, Internet of Things (IOT), Aviation, Artificial Intelligence, Privatization of Outer Space, Drones, Robotics, Virtual Reality, Ed-Tech, Med-Tech and Medical Devices and Nanotechnology with our key clientele comprising of marquee Fortune 500 corporations.

The firm has been consistently ranked as one of the Most Innovative Law Firms, across the globe. In fact, NDA has been the proud recipient of the Financial Times–RSG award 4 times in a row, (2014-2017) as the Most Innovative Indian Law Firm.

We are a trust based, non-hierarchical, democratic organization that leverages research and knowledge to deliver extraordinary value to our clients. Datum, our unique employer proposition has been developed into a global case study, aptly titled 'Management by Trust in a Democratic Enterprise,' published by John Wiley & Sons, USA.

Research@NDA

Research is the DNA of NDA. In early 1980s, our firm emerged from an extensive, and then pioneering, research by Nishith M. Desai on the taxation of cross-border transactions. The research book written by him provided the foundation for our international tax practice. Since then, we have relied upon research to be the cornerstone of our practice development. Today, research is fully ingrained in the firm's culture.

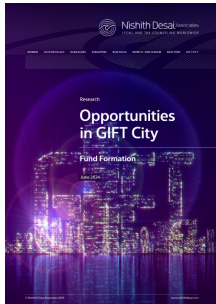
Over the years, we have produced some outstanding research papers, reports and articles. Almost on a daily basis, we analyze and offer our perspective on latest legal developments through our "Hotlines". These Hotlines provide immediate awareness and quick reference, and have been eagerly received. We also provide expanded commentary on issues through detailed articles for publication in newspapers and periodicals for dissemination to wider audience. Our NDA Labs dissect and analyze a published, distinctive legal transaction using multiple lenses and offer various perspectives, including some even overlooked by the executors of the transaction. We regularly write extensive research papers and disseminate them through our website. Our ThinkTank discourses on Taxation of eCommerce, Arbitration, and Direct Tax Code have been widely acknowledged.

As we continue to grow through our research-based approach, we now have established an exclusive four-acre, state-of-the-art research center, just a 45-minute ferry ride from Mumbai but in the middle of verdant hills of reclusive Alibaug-Raigadh district. Imaginarium AliGunjan is a platform for creative thinking; an apolitical ecosystem that connects multi-disciplinary threads of ideas, innovation and imagination. Designed to inspire 'blue sky' thinking, research, exploration and synthesis, reflections and communication, it aims to bring in wholeness — that leads to answers to the biggest challenges of our time and beyond. It seeks to be a bridge that connects the futuristic advancements of diverse disciplines. It offers a space, both virtually and literally, for integration and synthesis of knowhow and innovation from various streams and serves as a dais to internationally renowned professionals to share their expertise and experience with our associates and select clients.

We would love to hear from you about any suggestions you may have on our research publications. Please feel free to contact us at research@nishithdesai.com.

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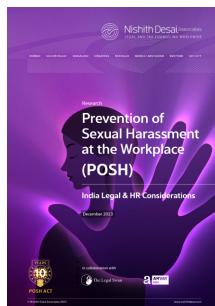
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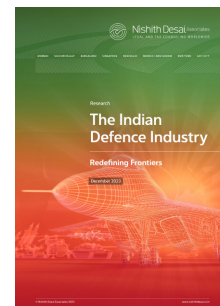
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