Chapter-IV

Various Socio-Legal Dimensions of DNA Technology

1. Introduction:

As we have already discussed in the introduction part of the doctrinal work that DNA Technology has multi-dimensional utility and application in today's world; and following it multidimensional application and dynamic nature it has created a deep impact on science, law, society, morality and ethical issues which all stands in conflicting situation amongst themselves and has also given rise to new issues and challenges for human society at large. It has both positive and negative effects on above-mentioned aspects. Therefore it is necessary for us to study it from all angles by keeping in to account the current Indian scenario with the cause and effect theory, as DNA technology has become indispensable part of life in present society.

1.1 Impact and application of DNA Technology on Society at large:

"Persona conjeneta aequiparatur interesse proportion": Proximity of blood and one's own interest are equivalent.

DNA finger printing, as a novel method to identify individuals has the applications in various other issues under mentioned spheres, such as:

- In criminal and civil case (administration of justice).
- Human population – The DNA FP has been applied in many popular cases like. Rajiv Gandhi case, Premananda Swami Case. Tandoor murder case, immigration case, Steve Bing case, Blue dress or Clinton Lewinsky case, OJ Simpson case,
- Plants genetics; for experiments, identification, inventions, medicines, creation and production, for establishing the Intellectual Property Rights.
- Bio-ethics
- Human enhancement
- Genetic weapons
- Genetic engineering

DNA finger printing has enormous impact on the administration of justice which can be studied in various Civil and criminal cases.

2 Use of DNA Information in the Legal System:

The use of DNA information can be bifurcated in the following types of cases for the sake of convenience:

- Investigation stage: In Criminal cases
- In civil cases

This chapter provides an overview of how DNA evidence might be used in the investigation and prosecution of crimes and in civil litigation.

RFLP is the technique most often considered by the courts to date. The criminal cases generally start with investigation stage and reaches to admissibility stage. The discussion of case laws and making a series of practical recommendations in this regard is very important, with judges especially in mind.

Investigation stage: In Criminal cases

The usefulness of the DNA technology in criminal cases can be explained with the help of following points:

- Well trained investigators: To produce biological evidence that is admissible in court in criminal cases, forensic investigators must be well trained in the collection and handling of biological samples for DNA analysis.
- They should take care to minimize the risk of contamination and ensure that possible sources of DNA are well preserved and properly identified. As in any forensic work, they must attend to the essentials of preserving specimens, labeling, and the chain of custody and to any constitutional or statutory requirements that regulate the collection and handling of samples.
- Legislatures while preparing DNA legislations must prepare much of the legal framework for the gathering of DNA samples from suspects or private places, and court orders are sometimes needed in this connection.

- Wherever possible, a preserved sample should be large enough to enable the defense to obtain an independent RFLP analysis, but there should almost always be enough at least for PCR analysis, a technique likely to be widely used in forensics in the near future for amplification of the DNA in the evidentiary sample.
- All materials relied on by prosecution experts must be available to defense experts, and vice versa.
- The laboratories used for analysis must be reliable and should be willing to meet recognized standards of disclosure.

2.2. Criminal Investigation:

DNA Technology is the most potent and accurate method to identify the criminals in cases where trace evidence fail to provide a conclusive proof as to who is the criminal. Through DNA technology, crime investigation has become more easy and accurate. Through DNA evidence collected from the crime scene, the criminal can be traced. It is of great use in the criminal cases related to Rape, Murder, Kidnapping, Robbery, and Burglary etc. and in cases where the body is in mutilated condition as in Tandoor Case, there DNA test is the only scope for investigation[71].

In India,more than sixty-nine cases have been solved with the help of DNA fingerprinting including paternity disputes. Even Dhanu and Sivarasan alleged assassins of the late Prime Minister Rajiv Gandhi, were identified by DNA profiles. Using this technique, the Federal Bureau of Investigations formally concluded on 17th August 1998, the day of Mr. Clinton's testimony before the grand jury, that the stain of the dress contained Mr. Clinton's DNA saying that there was only one in 7.87 trillion changes that it was not later on the formal finding was the truth.

The first criminal conviction based on DNA testing was in the 1986 U.S. case of Florida v Andrews[72], in which the DNA were compared for the purpose of identifying the perpetrator of a crime. The trial Court admitted the evidence, and the jury

[71] See, Tandoor murder case: Trial court verdict published on October 28, 2003 ,Available at http://in.rediff.com/news/2003/oct/28tandoor.htm (Last accessed on: 3rd March, 2007)
[72] 533 So.2d US 841 (1988)

convicted defendant of aggravated battery, sexual battery and armed burglary of a dwelling. Thereafter various cases have been solved.

But there are few cases where DNA typing of non-human (plant and animal genetics) biological samples has been of use in criminal trials have involved identification of an individual rather than of determination of the species of origin. These cases have been unique, with title widespread application (e.g. snowball the cat and a palavered tree in Arizona), however the potential for widespread application is great, pet hairs have been transferred from suspects to crime scene and vice versa. One can imagine that plant subspecies determination or identification might be very useful for marijuana tracing. One can also imagine that grasses found on the shoes of suspects might be very important and common evidentiary specimen to link suspects to crime scenes. In these cases chances of availability of DNA fingerprint is much more than that of fingerprint.

A DNA test has confirmed that former Asam Gana Parishad[73] Minister Rajendra Mushahary was the biological father of the child whose mother had alleged that Mushahary had raped her twice and made her pregnant. The police had to seek the Court's permission for DNA profiling when the investigation into the rape case had reached the dead end only for this unique technique. It is peculiar that demand is going on death penalty for rape but is it not desirable to go for a DNA test in rape cases to reach to a conclusion easily. This will be certainly a good piece of evidence against the accused. It will also eliminate false charges of rape[74].

It is the technique that investigators used to expose the attempt to pass off the killing of five innocent civilians in Jammu and Kashmir as that of terrorist. To ascertain the identity of the dead the Government obtained DNA samples of the corpses to match them with the blood samples of their relatives[75].

DNA fingerprinting is at the cutting edge of forensic science. If DNA fingerprinting works and receives evidentiary acceptance. It can constitute the single greatest

[73] A regional political party from north-eastern state of Assam
[74]Tandoor murder case: Trial court verdict published on October 28, 2003, Available at http://www.rediff.com/news/2001/aug/06rape.htm (Last accessed on: 24th March, 2007)
[75] Ibid.

advance in the search for truth and the goal of convicting the guilty and acquitting the innocent since the advent of cross-examination.

Once a result is obtained from a DNA sample the interpretation is crucial to the correct understanding of what the result means, and this result depends on how the results are expressed, which in turn depends on what questions are asked. Asking the wrong question can mislead Judge and this is what is called the Prosecutor's Fallacy.

Before going further it is important to mention how exactly DNA match probabilities are represented. A statistical theorem known as Bayes Theorem is widely in use in courts and it can be represented as follows[76]:

(Prior ODDS) x (Likelihood Ration): (Posterior Odds)

The strength of DNA evidence is conditioned by the "prior odds" on the accuser's guilt. It is the expert witness's task to present the likelihood ration (the match probability) to the Court. The Judge's task is then to multiply the likelihood ratio by the prior odds (their assessment of the probability of the defend ant's guild before hearing the DNA evidence).

This will then produce the posterior odds, the assessment of the probability that the defendant is guilty given the DNA evidence and the other evidence presented during the trial. If the prior odds are extremely low, then the impact of the DNA evidence will be dramatically reduced.

On the finding of a match the following few questions become relevant, for example,

a. In paternity dispute the question, did a sample originated from the individual?
b. DNA is of no relevance as it is well known where the sample came from?
c. On the other hand a question on similar lines would be relevant in a criminal case or not?
d. Given that the accused is innocent what is the probability that the DNA profile from the accused matches the profile, which came from the crime scene?

[76] See, Mike Redmayne, "DNA evidence probability and the courts", *1995 Criminal Law Review*, p. 464 and also Russell Stockdale and Clive Walker, "Forensic Evidence" in Justice in Error, Clive Walker and Keir Starmer (eds), *London*, 1993, p.77., Available at http://www.lawlink.nsw.gov.au/lawlink/pdo/ll_pdo.nsf/pages/PDO_dna

e. Given that the DNA profiles match from the accused and the crime scene, what is the probability that the defendant is innocent?

The scientific experts is only competent to answer the first question, he is not in a position to answer the second question as the answer may necessarily depend on factors apart from the DNA evidence in a case. The latter is a question to be answered by the Judge or the jury, as the case may be. Essentially the prosecutor's fallacy occurs when the answer to the second question is taken as the answer to the first.

The issue of the prosecutor's fallacy came up before the Court of Appeals in a significant manner in R. V. Doheny and Adams[77].

In the facts of this case D was convicted of rape and buggery, and A was convicted of buggery. In each case the prosecution placed substantial reliance on the results derived from a comparison between DNA profiles obtained from a stain left at the scene of the crime and DNA profiles obtained from a sample of blood provided by each appellant. In each case the appellant appealed against conviction on the ground of the possibility of shortcomings in the DNA evidence and the manner in which it was presented to the jury. When asked in examination in chief what was the likelihood of the offender being anyone other than D, the forensic scientist answered that it was about I in 40 million; he went on to affirm that he was sure that D was the offender. Despite the Judge reminding the jury of the other evidence, the overall effect of the Judge's summing-up was that if the jury accepted the forensic scientist's evidence, then D was guilty. It was for the jury to decide whether it was the accused who had left the crime stain or whether it might have been one of the other persons who shared with him the same DNA profile.

The important general principle that can be derived in this case is that it is important that scientist, in given evidence, should not go into matters which were for the Judge. He should explain the nature of the DNA match and give the random occurrence ratio;

[77] (1997) US 1 Cr App R 369

he may be able to say how many people with matching characteristics are likely to be found in the country or in a more limited sub-group.[78]

i. For identification purpose:

Identification of a criminal and connecting it with crime is the paramount purpose in a criminal trial and DNA-technology serves this purpose. Very often criminals leave on the crime spot many elements inadvertently like blood, hair, skin cells and many other genetic evidences, if these are collected & compared through VNTR Patterns with the DNA of a criminal, he can be spontaneously identified.

For example, in many heinous crimes, the offenders leave the cadaver by severing the head of the victim on the crime spot, leaving on the spot the head-less corpse; very often it becomes difficult to identity a dead body without head. In such a situation DNA-test can solve the problem. These types of incidents very often happen on a railway track. Particularly in the remote villages, in committing murder, the dead-body is kept hidden inside a deep pond for long days. The dead-body being non-traceable for long aquatic creatures eat the human flesh resulting unworthy of identification of the decomposed body. In such a situation DNA-test can solve the mystery.

(1) DNA is generally used to solve crimes in one of two ways. In cases where a suspect is identified, a sample of that person's DNA can be compared to evidence from the crime scene. The results of this comparison may help establish whether the suspect committed the crime.

(2)In cases where a suspect has not yet been identified, biological evidence from the crime scene can be analyzed and compared to offender profiles in DNA databases to help identify the perpetrator. Crime scene evidence can also be linked to other crime scenes through the use of DNA databases.

[78] See "DNA evidence the prosecutor's fallacy: The role of Expert and suggested Directions to the Jury on Random Occurrence Ratio", 1997, Published in *Criminal Law Review* 669, available at www.cps.gov.uk

ii. For baby-exchanging cases:

In many parts of India there is illegal practice of newborn baby exchanging in the Hospitals. The real biological parents are deprived of their original babies.

Generally a female baby is exchanged with a male baby. The mother is deprived of her original baby. This is a cheating of the worst kind. Such type of practice is prevailing in different parts of India. But DNA test in such situations has solved the mystery. Who is the actual real mother of the disputed baby can be ascertained by DNA test.

iii. Rape Cases:

In Rape Cases, DNA has enormous applications. Immediately after the commission of rape, if the vaginal Swab is collected and sample sealed and semen if collected from the accused and both samples are examined in the DNA laboratory, it can be ascertained with greater accuracy, if there is complete matching between these two samples[79].

For example, assume that a man was convicted of sexual assault. At the time of his conviction, he was required to provide a sample of his DNA, and the resulting DNA profile was entered into a DNA database. Several years later, another sexual assault was committed. A Sexual Assault Nurse Examiner worked with the victim and was able to obtain biological evidence from the rape. This evidence was analyzed, the resulting profile was run against a DNA database, and a match was made to the man's DNA profile. He was apprehended, tried, and sentenced for his second crime. In this hypothetical case, he was also prevented from committing other crimes during the period of his incarceration.

(d) Murder Cases:

In murder cases[80], DNA fingerprinting technique may be used for detection of the culprit who has committed murder. Different types of trace elements may be available

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[79] See, Article available at http://www.nytimes.com/1988/02/06/us/rapist-convicted-on-dna-match.html (Last accessed on: 12th June, 2007) Published: February 06, 1988

[80] Madhumita Shukla Murder Case where state politician Amarmani Tripathi was the main accused.

in the crime spot such as blood, hair roots etc. In many cases blood-stained clothes of the victim may be recovered from the possession of the accused or the bloodstained weapon, sword, bhojali, dagger etc. may be recovered fro the possession of the accused. All these elements are valuable materials for DNA test, which signifies presence of accused on the crime-scene. This means that old cases can now be solved and possibly prosecuted using current forensic technology. Similarly, in Trikambhai vs. State of Gujrat[81], the Gujrat High Court convicted solely on the basis of circumstantial evidence with corroboration of button and saliva on bidi found at the place of offence.

The other various types of acts and offences cases are as under where DNA Technology can be used.

(e) Kidnapping (Aggravated form)

(f) Infanticide,

(g) Abandonment of child,

(h) Illegal abortion,

(i) Immigration,

(j) Inheritance

(k) Assassination.

(l) In Paternity and Maternity disputes: VNTR (Variable number tandem repeats) analysis can conclusively determine the parentage of a child. This is possible because a person inherits his or her VNTRs from his or her parents.

"*confirm actio omnes supplet defectus licet id quod actum est ab inition non velait*", Though something has done not valid confirmation, cures all defects. So, in this regard if the confirmation of the DNA evidence is directed it would be easy for convicting accused.

[81] AIR 2009 Guj.224

(m) For General identification of Criminals

(n) For detecting innocence of many suspects: DNA technology is not only helpful for crime detection and identifying criminals, it is also helpful for exonerating many innocents from the trap of malafide criminal prosecution.

(o) Personal Identification: DNA fingerprinting has an outstanding characteristic for identifying a person amidst millions of people. The U.S. armed services have begun a program to collect DNA fingerprints from all personnel for use later, in case they are needed to identify casualties or persons missing in action. The DNA method will be far superior to the dog tags, dental records and blood typing strategies currently in use.

(p) DNA Records: Every plot of land has a definite plot number for identification. But man has until now no so much well-defined record of identification. But DNA can solve this problem. Days are not far away from us when each family will maintain DNA records for identification purpose and that will be the best method of scientific identification and that will help the administration of justice in future.

(q) Designing a baby: Until the last few decades, it was not possible to determine the sex of a child. But now with the latest genetic testing technique, one can decide the sex of their child with greater accuracy. Manique and Scoot Collins had a long dream daughter Jessica after genetic pre-screening at a fertility clinic in Fairfax Virginia. Thus, within a decade or two, it may be possible to screen kids almost before, conception for a wide range of attributes, the height, the size, the colour, even the I.Q. and personality. In the near future, parents may go to fertility clinic and pick up from a list of options the way car buyers order air-conditioning, stereo etc. It is the ultimate shopping experience "designing a baby". All these advances in science have a serious impact on the administration of criminal justice[82].

(r) In affiliation, ward ship, testacy, or divorce proceeding

(s) For immigration authorities for clear evidence of a familiar relationship.

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[82]See, "Rapist Convicted on DNA Match",*The New York Times*, February 06, 1988 Available at http://www.nytimes.com/1988/02/06/us/rapist-convicted-on-dna-match.html (Last accessed on: 12th June, 2007)

(t) In veternity field where pedigree confirmation is required.

(u) In the field of Medicine for diagnosis of genetic diseases.

(v) In Agriculture for identification of seeds stocks and germ-plasm.

3. DNA and Criminal Cases:

"habemas optimum testem confitentem reum" -The best witness is the accused himself who confesses his guilt.

But if the accused dose not confesses his guilt then the DNA Technology is the best option to reach to the facts.

Despite the issues and evidentiary hurdles that have been referred to in the course of this project. Indian Courts have accepted the evidence of DNA experts. Unlike the area of paternity disputes where there seems to be some degree of controversy in the field of criminal law Courts have readily accepted DNA evidence in India. So far however, there have been no convictions solely on the basis of DNA evidence.

One instance of the application of DNA profiling/fingerprinting evidence being used to convict the accused persons can be seen in the case of Chandradevi V. State of Tamil Nadu.[83] This sensational case involved the rape and murder of several teenage girls in the Ashram of a god-man Premananda alias Ravi, by the god man and his accomplices.

In a lengthy judgment the Madras High Court considered 4 important questions: -

1. Whether the DNA evidence is generally accepted by the scientific community?

2. Whether the testing procedure used in this case is generally accepted as reliable, if performed properly?

3. Whether the tests were performed properly in this case?

4. Whether the conclusion reached in this case is acceptable?

[83] See, "Relevance of DNA Evidence in Sexual Offences", *Central India Law Quarterly* (2008) Available at MANU/tn/2335/2002.(Last Accessed on 3oth June 2007)

In answering the first question the Court relied on the extent to which Courts in the United States had relied on evidence of DNA analysis. The 2nd, 3rd and 4th questions were all answered in the affirmative and the accused persons were convicted on various counts on the basis of the evidence of experts on DNA fingerprinting/profiling and other evidence. However, in another case M. V. Mahesh v. State of Karnataka[84], the Court acquitted the accused, one of the grounds being that the requisite amount of DNA of high molecular weight was not present so as to make the test results sufficiently conclusive and accurate. The Court further went on to say that the DNA test was not a fool proof one and also commented on the fact that there were no national standards set or established for DNA testing in India.

Such scrutiny of the DNA testing procedure is commendable and any benefit of doubt arising from malpractices or irregularities in the scientific processes involved ought to go to the accused murder, rape, kidnapping, offences against body.....etc Old , cold, or unsolved cases that were previously thought unsolvable may contain valuable DNA evidence capable of identifying the perpetrator.

4. The Admissibility of DNA Evidence:

res judicata pro verilate accipitur, a decision of court is accepted as evidence of truth.

The discovery of DNA technology has profound impact not only in the field of genetic biology, but also in the field of law enforcement. The creation of the first DNA criminal investigative database in 1995 in Briton enabled law enforcement to better exploiting uses of DNA technology. The DNA technology has provided great advantages in the legal community. The technology has been useful in criminal investigation and also in civil disputes, such as, paternity disputes. The question therefore arises in the courts as to whether such scientific evidence as DNA should be considered in a given case. Under Section 45 of the Indian Evidence Act, 1872, it has been, inter alia, provided that, when the court has to form an opinion upon a point of science, or art, or as to identity of handwriting or finger impression, the opinions upon that point of persons specially skilled in science or art or any question as to identity of

[84] 1996 Cri LJ221 (Kant),

handwriting or finger impressions are relevant facts and such persons are called experts. The expression opinions upon a point of science of persons especially skilled in science are capable of application to all future advances in science, which enable an expert opinion on a point.

The original test for the admissibility of DNA and other scientific evidence was developed in Frye v. United States[85], and is commonly known as the "Frye standard". The Frye opinion is remarkable both for its brevity and for its lack of citational adornment. The appellant who was convicted of the crime of murder contended that the trial court had committed an error in sustaining the objection by counsel of the government against the offer of the defendant (accused) of an expert witness to testify to the result of the systolic blood pressure deception test to which the defendant was subjected prior to the trial. The theory underlying the test was that "truth is spontaneous, and comes without conscious effort, while the utterance of falsehood requires a conscious effort, which is reflected in the blood pressure". The Court of Appeal of District of Columbia held:"..... And while courts will go a long way in admitting expert testimony deduced from a well recognized scientific principle or discovery, the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field it belongs." "We think the systolic blood pressure deception test has not yet gained such standing and sufficient recognition among physiological and psychological authorities as would justify the Courts in admitting expert testimony deduced from the discovery, development and experiments thus far made. The judgement is affirmed." Thus, when MtDNA / PCR testing were new and done by only a few laboratories they would not have been treated as admissible under the Frye standard, which asked the courts to determine whether the scientific evidence in question has "gained general acceptance in the particular field in which it belongs". Frye Standard was considered to be a roadblock to admissibility of even efficacious evidence simply because the techniques were recently discovered. There was therefore a need for a fresh look on the aspect of admissibility of scientific evidence in courts[86].

[85] 293 F.1013 (DC Cir.1923)

[86] See, Honourable Mr.Justice R.K.Abichandani, "The Gene Age – A Legal Perspective", Available at http://gujarathighcourt.nic.in/Articles/legalpers.htm. and 54 App. D. C. 46, 293 F. 1013 No. 3968

The breakthrough came in 1993 when the U.S. Supreme Court in Daubert v. Merrell Dow Pharmaceuticals, Inc.[87], held that the Frye's "general acceptance" test was superseded by the Federal Rules of Evidence which provided the standard for admitting expert scientific testimony in a federal trial.[88] It was held that nothing in the text of the rule established "general acceptance" as an absolute prerequisite to admissibility. It was, however, held that the fact that the Frye's test was displaced by the Rules of Evidence did not mean that the Rules themselves placed no limits on the admissibility of purportedly scientific evidence. Nor is the trial Judge disabled from screening such evidence. "To the contrary, under the Rules, the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable". It was held that, "the requirement that an expert's testimony pertain to "scientific knowledge" establishes a standard of evidentiary reliability". The key question to be answered in determining whether a theory or technique is scientific knowledge that will assist the court will be whether it can be tested or and has been tested.

The Court held that "general acceptance" is not a necessary precondition to the admissibility of scientific evidence under the Federal Rules of Evidence which assigned to the trial judge the task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand. Pertinent evidence based on scientifically valid principles will satisfy those demands. The court noted that there are the important differences between the quest for truth in the courtroom and the quest for truth in the laboratory, observing: "Scientific conclusions are subject to perpetual revision. Law, on the other hand, must resolve disputes finally and quickly. Broad advances the scientific project and wide-ranging consideration of a multitude of hypotheses, for those that are incorrect will eventually be shown to be so, and that in it is an advance. Conjectures that are probably wrong are of little use, however, in the project of reaching a quick, final, and binding legal judgment – often of great consequence – about a particular set of events in the past. We recognize that, in

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Court of Appeals of District of Columbia, united states (1923),available at http://www.caselaw4cops.net/searchandseizure/evidence.htm(accessed on: 24th April, 2007)

[87] 509 U.S. 579 (1993)

[88] Rule 702 governing expert testimony provided: "If scientific, technical, or other specialized knowledge will assist the tried of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise".

practice, a gate-keeping role for the judge, no matter how flexible, inevitably on occasion will prevent the jury from learning of authentic insights and innovations. That, nevertheless, is the balance that is struck by Rules of Evidence designed not for the exhaustive search for cosmic understanding, but for the particularized resolution of legal disputes.[89]"

In order to determine whether scientific evidence is admissible, the court may consider – (1) whether the principle or technique has been or can be reliably tested, (2) whether it has been subjected to peer review or publication, (3) its known or potential rate of error, (4) whether there are standards or organizations controlling the procedures of the technique, (5) whether it is generally accepted by the community, and (6) whether the technique was created or conducted independently of the litigation. The Daubert test which still allows for consideration of "generally accepted" factor as one of the factors has somewhat increased the admissibility of DNA procedure, because, now newer tests can be recognized depending upon their authenticity and effectiveness.

In USA, the famous O. J. Simpson's case was decided mainly on the basis of DNA profiling. In India too, DNA Technology is used for solving serious problems of crime detection /investigation and other relevant cases. Gautam Kundu Vs State of West Bengal[90] Sajeera Vs P.K Salim [91], etc. are some cases in which DNA evidence was relied on. In India, there are more than 1500 cases in which DNA testing was taken into consideration for solving the problem of law enforcement. In USA over five-thousand cases resulted in conviction without any investigation thanks to DNA Technology. This makes its clear that it aids in the\ advancement of justice as it helps the police, prosecutors, public –in searching the truth, not only this, the technology has been used to exonerate innocent persons in post conviction stages. But DNA Technology has raised two important issues in front of legal fraternity namely determining admissibility and explaining the standard of weighing evidence,

[89] 509 U.S. 579 (1993)
90 AIR 1993 SC 2295
91 17 2000 Cr.L.J. 108
92 17 2000 Cr.L.J. 108

including other related questions like experts evidence etc. The Frye Test[92] in USA has solved the problem by laying down three important guidelines popularly called as Frye Rule.

These are as follows: -

Rule 1: Whether DNA technology is a science and is accepted so in world community.

Rule 2: Is there any technology to establish Rule 1.

Rule 3: Whether the technology is properly applied.

These rules have established the admissibility of DNA evidence in the legal system. The courts in USA have taken judicial notice of DNA evidence. Several States in USA have enacted laws that essentially mandate the admission of DNA evidence because of its potential powers of definitive identification. In short it can be said that it has climbed from circumstantial evidence to real evidence. In USA there are two enactments namely the Innocence Protection Act, 2003 and The Advancement of Justice through DNA Technology Act, 200320 lay special emphasis to use DNA Technology. The first act favours a person, who is being wrongly convicted; in fact it is a model statute for obtaining post conviction DNA testing.

5 Role of Expert:

"cuilitbet in arte perito est credendem", The credence should be given to one who is skilled in his peculiar Profession.

Through it is well known that an individual's DNA is unique to him/her. What is often not realized is how much of an individual's DNA is in common with that of other individuals[93] Therefore, the scientific expert only has a part of the entire sequence of the individual's genome available for him to make his judgment. This

[92] As evolved in Frye v. United States, 293 F2d. 1013 (DC Cir.1923)

[93] See, Denial Burke and Denial Whiteman, "*Argue with science*? The admissibility Debates surrounding DNA identification", Available at www.biology.arizona.edu. (accessed on15th April, 2007)

clearly has a bearing since the judgment is bared not on the whole but only a part of the possible material and therefore all that more difficult.[94]

How DNA evidence is and should be presented in a Court of law is also an important question, which requires attention. It is also examines the evidentiary aspects of DNA fingerprinting with respect to both civil and criminal cases.

a. DNA and Probability, Some Issues:

As stated earlier, an individual's DNA is unique to that individual. However, much of our DNA is common with the rest of the living world and also with other individuals. This makes differentiation between individuals with absolute certainty very difficult. For this reason much of DNA fingerprinting evidence is in terms of probabilities.

b. Presentation of DNA Evidence in Court:

There is fundamental difference between how DNA evidence is presented and how other kinds of identification /identity evidence is presented in a Court of law. The difference has more to do with the fact that unlike DNA evidence, earlier types of identification evidence are not derived from a coherent body of data and statistical reasoning.

It would be useful to compare the evidence of an expert on fingerprints and the evidence of an expert in the case of DNA. A fingerprint expert gives an opinion, usually by stating that he/she is certain that the sample belongs to the person/accused. On the other hand the DNA expert gives an opinion by presenting the evidence in the form of a numerical statement known as a match probability.[95]

c. DNA Evidence is not infallible:

Due to the fact that each individual's DNA is unique to him or her, the perception that DNA evidence is infallible is created. These perceptions of infallibility are in fact

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[94] In at least one Indian case Chandrasdevi and others v. State of T.N., the court has relied on expert evidence on DNA evidence that has stated that out of 3.3 billion base pairs only about 3 million vary from person to person. I.e. 1% DNA is useful for analysis, Available at manu/tn/2335/2002

[95] LAN Evet, Lindsey Foreman, Graham Jackson and James Lambert, "DNA profiling: a discussion of issues relating to the reporting of vary small match probabilities", *Criminal law review*, 2008, p. 341,Available at http://www.alrc.gov.au/publications/44-criminal-proceedings/presentation-dna-evidence(Last Accessed on July 12 2007)

unfounded. There are two important factors to be taken into consideration in this regard.

- Apart from the fact that there may be errors in the testing process, there is also the major question of statistical reliability. It must always be remembered that even where the probability that a sample comes from Person X is 1 in 1 crore. One cannot rule out the Possibility that the sample came from another person. That is the very nature of probability of evidence.[96]
- Another very important factor is that DNA evidence should not be looked at in isolation.[97] This is particularly true of criminal cases where the burden of proof is usually on the prosecution and the case has to be proved beyond reasonable doubt.[98]

d. Expert Evidence and the Prosecutor's Fallacy

One of the most interesting and some what controversial issues with respect to DNA analysis relate to the opinion and role of the scientific expert in the courtroom. Like all other scientific evidence, DNA evidence also has to be proved and this is done with the aid of the testimony of an expert[99].

Before proceeding further, it is important to set out the relevant provisions of the Indian Evidence Act, which apply to expert testimony with respect of DNA evidence. DNA Fingerprinting and analysis is almost invariably with respect to matters relating to identification. S-9 of the Indian Evidence Act is important in this regard and it speaks of facts that are necessary to explain or introduce relevant facts.[100] As far as Expert testimony is concerned Ss. 45 and 51 are of particular relevance. S. 45 speak

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[96] In the field of probability, it is said that where the happening of the certain event is certain the probability of that event is expressed as 1. As far as DNA evidence is concerned, current scientific methods do not provide for a match probability of 1.

[97] Supra Note 97

[98] To illustrate this point the following example may be used – The DNA evidence points to the fact that person X was at the scene of the crime at 9.30 pm. However there is also evidence by way of testimony of witness and the recording of the security camera that person X was at a particular place. Assuming that the person does not have a twin, person cannot be convicted on the basis of DNA evidence in light of the other evidence. Either an error has been taken place during testing or another person has the same DNA match as person X.

[99] R. V. Doheny and Adams , (1997) 1 Cr App R 369.(case where prosecutor's fallacy came into picture)

[100] The relevant portion of sec-9 of the Indian Evidence Act reads as follow..."Facts...which establish the identity of anything or person whose identity is relevant...are relevant in sons far as they are necessary for that purpose."

about the evidence of experts generally. [101]S. 46 speak about the facts bearing on the opinion of experts,[102] while S. 51 deals with the relevancy of the grounds on which the opinion of an expert is based. [103]

Efficiently cover the opinion given by an expert of DNA, through they were drafted some time before the discovery of DNA. It is also crucial that while dealing with DNA analysis the right questions be asked depending on the facts and circumstances of the case.[104]In this regard two major kinds of cases are examined in this section, namely, criminal cases and cases relating to parentage.

e. Post- conviction DNA Testing:

Post conviction DNA testing has received considerable attention in recent years. Since the advent of forensic DNA analysis, a number of people convicted of crimes have been subsequently exonerated through DNA analysis of crime scene evidence that was not tested at the time of trial.

"Nemo Punitur Pro Alieno Delicto", No one should be punished for the wrongs of another.

The DNA Technology must be used after conviction of the person. DNA technology is not only useful for strengthening cases against suspects but has become extremely helpful in probing innocence of suspects and even past convicts. DNA testing has proved the innocence of convicted felons in many cases. The National Institute of Justice under the guidance of Former Attorney General Janet Reno, issued a report in 1996[105], stressing importance of the use of DNA evidence to exonerate the innocents. The report provided twenty-eight case studies where the use of previously unavailable DNA technology proved the innocence of convicted felons. These twenty-eight men

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[101] Sec-45 –Opinion of an Expert: "When the court has to form an opinion upon a point of foreign law or science or art .....Such person is called experts.'

[102] Sec-46-Facts bearing on the opinion of the expert-"Facts not otherwise relevant are relevant if they support or are inconsistent with the opinion of the expert when such opinions are relevant.'

[103] Sec-51"Whenever the opinion of a living person is relevant, the ground on which such opinion is based are also relevant." Also see: Mike Redmayne,"DNA evidence probability and the courts,", 1995, *Criminal Law Review*, 464,Available at www.lawlink.nsw.gov.

[104] For example in paternity dispute the question 'Did a sample originated from the individual? Is of no relevance as it is well known where the sample came from. On the other hand a question on similar lines would be relevant in a criminal case.

[105] entitled "Convicted by Juries, Exonerated by Science: Case Studies in the Use of DNA Evidence to Establish Innocence After Trial", USA, 2006

in the study had served an average of seven years in prison before exoneration. Three years after the initial report, the National Commission on the Future Use of DNA Evidence issued another report entitled "Post Conviction DNA Testing: Recommendations for Handling Requests. This report was aimed at highlighting legal and scientific issues involved in post conviction testing and provided recommendations for prosecutors, defense counsel, the judiciary, victim assistance groups, and laboratory and law enforcement personnel. The post conviction cases highlight the importance of DNA technology and more specifically DNA database, as an investigative tool. [106]

The DNA evidence is now a predominant forensic technique for identifying criminals when biological tissues are left at scene of crime. DNA testing on samples such as saliva, skin, blood, hair or semen not only helps to convict but also serves to exonerate. The sophisticated technology makes it possible to obtain conclusive results in case in which the previous testing had been inconclusive. Post-conviction testing will be requested not only in cases in which the DNA testing was never done, but also in cases in which more refined technology may result in an indisputable answer. The Working Group on Post Conviction issues under the aegis of the National Commission on the future of DNA Evidence published a report[107] on the subject DNA victims' rights and restorative justice. The document discusses the kind of legal issues that had already arisen and others that will probably develop as applications for post conviction DNA testing continue to be made and the technology to conduct those tests advances. The probative value of DNA testing has been steadily increasing as technological advances and growing databases expand the ability to identify perpetrators of crime and eliminate the suspects. The strong presumption that verdicts are correct, one of the underpinnings of restrictions on post-conviction relief has been weakened by the growing number of convictions that have been vacated because of exclusionary DNA results. As observed in the report, DNA evidence gives rise to thorny legal issues, because post-conviction requests for testing do not fit well into the existing procedural schemes or established constitutional doctrine.

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[106] See, Allison Puri "*An International DNA Database: Balancing Hope, Privacy, and Scientific Error*," Allahabad Law Agency, 2003, p.189

[107] See, U.S. department of Justice, "Post Conviction DNA Testing: Recommendations for Handling requests", September 19, 1999 ,For comments on the case see "DNA Evidence the prosecutor's Fallacy-The role of expert-suggested directions to Jury on random Occurance Ratio"1997 *Criminal Law Review*, p. 669.

By issuing orders, the Court can play an important role in helping to obtain access to evidence prior to testing, which is part of the screening process and helps determination if DNA evidence will be relevant to the case. In cases in which the biological evidence was collected and still exists, and if the evidence is subjected to DNA testing or re-testing, exclusionary results will exonerate the petitioner or support his claim of innocence, the court can issue orders permitting DNA testing or re-testing. Once post-conviction DNA test results have been obtained, if the results are favorable to the inmate and no alternative explanations exist, the court should be prepared to grant a joint request to vacate the conviction and in the absence of a joint request, an evidentiary hearing should be set to determine if there is a reasonable probability of a change in the verdict or judgment of conviction. In jurisdictions where conviction cannot be so upset on a joint request and appellate remedies are already exhausted, the clemency powers of the sovereign State can be invoked by forwarding an appropriate recommendation on the basis of the outcome of such DNA testing or re-testing.

In the Indian context, the Constitution empowers the President of India under Article 72 and the Governor of a State under Article 161 to grant pardons, reprieves, respites or remissions of punishment or to suspend, remit or commute the sentence of any person convicted of the offences referred to hereunder.

It is obligatory on the laboratory to perform quota DNA tests and to interpret and report the results accurately and without bias. The database can be helpful for linking previously unrelated cases and for screening and large number of known individuals already convicted of a crime. A "cold hit" from a database can prove to be a boon to a person undergoing sentence for proving his innocence. It would however appear that the need for post-conviction DNA testing will wane over a period of time when DNA testing with high discriminatory results will be performed in all cases in which biological evidence is relevant, and advanced technologies will become commonplace in all laboratories. Coordination among prosecutors, defense attorneys, law enforcement agencies and crime laboratories is required[108].

[108] The duties, responsibilities of prosecutor, defense lawyers, and judiciary etc. while dealing with post conviction cases have been discussed in the conclusion part of the research work.

6. Use of DNA Technology in civil cases, such as paternity, custody, and proof of death cases, succession and property;

- The standards for admissibility must also be high, because DNA evidence might be dispositive. It is important to distinguish between civil and criminal cases in determining the admissibility of scientific data while preparing DNA legislations.
- In a civil case, however, if the results of a DNA analysis are not conclusive, it will usually be possible to obtain new samples for study. As in criminal cases, laboratories and other interested parties must treat evidence according to established protocols.
- The advent of DNA typing technology raises two key issues for judges: determining admissibility and explaining to the prosecution and defence lawyer and parties to the case the appropriate standards for weighing evidence. The role of expert for expert evidence plays a noteworthy role, therefore the responsibilities and role of expert during such civil as well as criminal trials must be demarked by legislation by introducing a different chapter in DNA.

6.1 Law Relating To Parentage Related Issues- Paternity And Maternity: This can be explained under the following heads:

a. Parentage Testing
b. Evidence
c. Identification

a. Parentage testing:

"affirmanti non neganti incumbit probation", The burden of proof lies up on him who denies and therefore DNA Technology is used where the person denied paternity and the burden of proving this lies on him.

Parentage testing refers to testing done to confirm or deny biological parentage of a particular child or individual. Such testing may be conducted by blood group or DNA analysis. DNA parentage testing may exclude a person as the biological parent of a child with certainty but it cannot prove absolutely that a person is the child's

biological parent. The test result can, however, provide a probability that a person is the biological parent of a child and, if that probability is sufficiently high, an inference of parentage may be confidently drawn[109]. Parentage testing is relationship testing and requires participation of two, sometimes three individuals in order to reveal useful information about biological relationship between those persons. The context in which outcome of parentage testing is revealed is often highly emotionally charged. Where parentage has been misattributed, there may arise issues of "betrayal, revenge, truth and the search for resolution" for many years. This raises the question whether law should emphasize biological parentage over social parentage in matters of parental responsibility, guardianship and maintenance, succession and so on.

DNA parentage testing may be used to rebut a presumption arising under the Act, or to establish evidence in the circumstances where no presumption arises. A man might seek DNA parentage testing in order to obtain evidence of non-paternity for the purpose of civil proceedings against the child's mother to prove "paternity fraud" and claim damages for emotional stress and financial loss that he suffered due to such fraud. DNA parentage testing may provide evidence to show that a person has a biological connection with a deceased person and can be a proof in support of a succession claim. In mass disasters, such as, airplane crashes and the World Trade Centre collapse, DNA parentage and relationship testing is increasingly used in identifying human remains where the body of the deceased is no longer recognizable.The scientific accuracy of parentage testing is of vital importance, whether it is conducted by accredited or unaccredited laboratories. In a case where the family court ordered a man to undergo DNA parentage testing in relation to a child of whom he claimed to have no knowledge, the test result disclosed a 98.5% probability that he was the father of the child and was required to pay maintenance for the child, years later, the man's brother admitted having had a relationship with the child's mother, and parentage testing showed a 99.5% probability that the brother was the child's father[110]. The social, psychological and economic consequences of unreliable

[109] See, ALRC Discussion Paper 66, "Protection of Human Genetic Information, DNA Parentage Testing", 2001,Available at www.alrc.gov.au/inquiries/protection-human-genetic-information(Last accessed on 21st May 2007)

[110] See, case reported in G. Bearup, "The Doubt about Dad", The Good Weekend ,*The Sydney Morning Herald*, 3rd November 2001, 16, 20, and is referred in paragraph 31.42 of the ALRC Discussion Paper 66, Available at www.alrc.gov.au/inquiries/protection-human-genetic-information(Last Accessed on 21st May 2007)

testing point towards an imperative need to maintain the highest technical, scientific and professional standards in conducting parentage testing. It is suggested that parentage testing be done under supervision of courts to ensure both the accuracy and reliability of the evidence admitted. Possibility of 'DNA fraud' by laboratory staff in such tests is a matter of grave concern and there should be a proper mechanism to address issues arising from the test results and for safeguarding and protecting the integrity of samples against tampering or deliberate fraud. The option of using court supervision would make parentage testing subject to a court order and would enable the courts to provide independent oversight of testing, including in relation to the validity of consent.

Legislation should be enacted to ensure that only government-recognized laboratories in accordance with the regulatory requirements that may be statutorily laid down conduct DNA parentage testing in India. Family Courts Act should be amended to provide a special chapter dealing with DNA parentage testing and adequate provisions should be made there under to ensure that parentage testing meet the highest technical and ethical standards, particularly in relation to consent to testing, protecting the integrity of genetic samples, and providing counseling. The parentage testing reports should be admissible in evidence only if made in accordance with the statutory requirements.

Law should recognize a child's right to give or withhold consent to the testing of his or her own genetic sample where the child has acquired sufficient maturity and understanding, of the process and its implications to safeguard his or her own interest. Legislation should provide for enabling a child above 12 years of age and having sufficient maturity to make a free and informed decision whether to submit a genetic sample for parentage testing. Paramount consideration should, however, in all events be the welfare of the child concerned.

Parentage cases, which involve disputes as to maternity, are quite rare. In any case the determination of maternity is somewhat more simplified because of something called mitochondrial DNA or Mt DNA [111]. Mt. DNA is peculiar since it is inherited only

[111]Mitochondria organelles within the cell those are responsible for the respiratory functions of the cells.

through the mother; it has great application in cases involving maternity disputes[112] but not so in cases involving paternity disputes. The usual two questions with respect to paternity disputed are as follows:-

A. Is there a suggested alternative father?

B. Is there a completely unknown father?

However, in both situations there is always a residual doubt that is attendant with evidence of probability of match.

3. The Rule of Law based on the dictates of the Justice has always made the Courts inclined towards upholding the legitimacy of the child, unless the facts are so conclusive and clinching as to necessarily warrant a finding that the child could not at all have been begotten to the father and as such the legitimacy of the child is rank justice to the father. Courts have always desisted from lightly or hastily rendering a verdict and that too, on the basis of slender material, which will have the effect of branding a child as a bastard and his mother as unchaste women. In view of the provision of Sec.112 of the Evidence Act, there is no scope of permitting the husband to avail of blood test for dislodging the presumption of legitimacy and paternity arising out of the Section28. Blood group test to determine the paternity of a child born during wedlock is not permissible.[113]

4. To determine child's parentage, there are statutory presumptions, such as, under Section 112 of the Indian Evidence Act[114], that the fact that any person was born during the continuance of a valid marriage between his / her mother and any man, or within two hundred and eighty days after its dissolution, the mother remaining unmarried, shall be conclusive proof that he is the legitimate child of that man, unless it can be shown that the parties had no access to each other at any time when that child could have been begotten.

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[112] ibid

[113] Smt. Dukhtar Jahan vs. Mohammad Farooq AIR 1987 SC 1049. and Gautam Kundu Vs Shaswati Kundu Criminal Revision No. 800/92 (Cal) and see also:,Tushar Roy vs Shukla Roy, 1993 Cr. L.J 1659 (Cal)

[114] "Birth during marriage, conclusive proof of legitimacy – The fact that any person who was born during the continuance of a valid marriage between his mother and any man or within during two hundred and eighty days after its dissolution, the mother remaining unmarried, shall be conclusive proof that he is the legitimate son of that man, unless it ca be shown that the parties to the marriage had no access to each other at any time when he could have been begotten."

The Hon'ble Supreme Court in Gautam Kundu Vs State of West Bengal[115] added some guidelines regarding permissibility of blood tests to prove paternity:

1. That the Courts in India cannot order blood test as a matter of course.

2. Whenever applications are made for such prayers in order to have roving inquiry, the prayer for the blood test cannot be entertained.

3. There must be a strong prima facie case in that the husband must establish non-access in order to dispel the presumption arising under Sec.112 of Evidence Act.

4. The court must carefully examine as to what would be the consequences of ordering the blood test.

5. No one can be compelled to give sample for analysis.

As compared to position in England, where keeping pace with modern thinking on the continuing and shared responsibility of parenthood, The Family Reforms Act, 1969 was replaced by The Family Reforms Act, 1987 which enabled the Judiciary to determine the parentage rather than paternity.

b. Evidentiary Aspects of DNA and Cases relating to Paternity Disputes:

In India DNA fingerprinting and analysis has been widely used in paternity cases[116]. Prominent among these is the effect of the new developments in forensics in the form of DNA profiling/fingerprinting and the case for an amendment to S.112 of the Indian Evidence Act dealing with conclusive proof in paternity cases[117].

In Smt. Kanti Devi v. Poshi Ram[118], the Apex Court held that the result of a genuine DNA test is said to be scientifically true. But even that is not enough to escape from the conclusiveness of Section 112 of the Act. e.g. if a husband and wife were living

[115] 30 AIR 1993 SC 2295

[116] See, Arukumar v. Turaka Kondalal Rao, 1998 Cri.L. J.4279 Where a single locus probe RFLP and STR analysis was carried out to prove the paternity of the child

[117] The other major issue with respect to paternity cases, on which there is much conflicting case, law deals with whether the Courts can direct one of the parties to give a sample of DNA and the effect of refusal to undergo a DNA test. This has obvious constitutional implications.

[118] AIR 2001 SC 2226

together during the time of conception but the DNA test revealed that the child was not born to the husband, the conclusiveness in law would remain un-rebbutable. This may look hard from husband's point of view. It is submitted public policy that children should not suffer the social disability on account of the laches or the lapses of parents. As per Modi's Medical Jurisprudence and Toxicology, there is a lot of chance that maximum period of the pregnancy can be above 280 days this section dose not apply to all critical situations to establish the legitimacy of the child the DNA testis the only method[119].

c. Parentage Identification:

The role of DNA test in parentage identification is also very important. Parentage identification means paternity and maternity identification. Parentage identification is necessary to prove the legitimacy of child. Maternity identification by DNA test is necessary in child abandonment case and infanticide. Paternity identification is necessary in the cases where financial support maintenance is to be given, property is to be inherited and in rape, sexual relation with consent, incest if pregnancy could not be terminated when it was detected. The first reported paternity case of DNA typing is in re Baby Girl.[120] Another important case of inheritance is Alexander where an illegitimate child claiming an inheritance permits it to disinterment for a DNA test.

7. Adultery:

Section 497 of Indian Penal Code, 1860 deals with Adultery. In cases of adultery, if the married women got conceived, suppressed this fact of pregnancy from her husband so on so forth, the husband could easily get confirmed of such pregnancy of his wife through her paramour. Further to know the chastity of the women and the sacredness of the nuptial contact, the DNA is very much needed to ascertain the truth or otherwise of such suspected pregnancy and infidelity of the wife, the husband can take the very extreme step of killing her[121].

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[119] See, Jaising P Modi, "*Modi's Medical Jurisprudence and Toxicology*",23rd Edition, 2007, Allahabad Law Agency, p. 540 to 542.

[120] In re Baby Girl M. (1984) 37 Cal.3d 65, 207 Cal.Rptr. 309; 688 P.2d 918, Available at http://scocal.stanford.edu/opinion/re-baby-girl-m-28396 (Last accessed on: 31st May, 2007)

[121] Gautam Kundu Vs State of West Bengal, 1993 Cri LJ, 3233

Section 497 of IPC prescribes no punishment for wives who indulge unlawful sexual intercourse without permission from her husband. But adultery can be one of the grounds for the refusal of maintenance in section 125 of Cr. P. C. This is no offence by the married wife, though she is betrayed her husband as no punishment is there for her wrongful act.

But exactly in opposite situation when the husband denies the maintenance to wife and his legitimate child by alleging wife for adultery, then in such situation the wife can claim maintenance by undergoing DNA Testing and can prove her innocence. Hence to avoid such unfortunate incidents, DNA test can be proved helpful.

8. Inheritance and Succession: *"deficiante uno non potest esse haeres"*, There being no utility of blood, one cannot be a heir.

"deas salus haerendum facere potest non homo", God Alone Can Make Heir Not Man.

Under Hindu Marriage Act, 1955 an illegitimate child (legitimized by the virtue of Sec 16) inherits the property of his parent's property in which the father is the coparcener.31 Thus under such circumstances to establish the legitimacy or illegitimacy of such children and to inherit the property, the DNA test is the only perfect medical evidence for in heritance or non inheritance of the properties[122].

9. Maintenance:

In case of the disputes relating to illegitimate child the DNA technology plays an important role to compel the father of the illegitimate of child to give him maintenance when he denies the paternity and maintenance.

Section 125, The Code of Criminal Procedure, 1973 states that it's the duty of the man to maintain his wife, legitimate or illegitimate children, parents as long as they can't maintain themselves. So the man can take the defence that the children doest belong to him. So in these situations DNA test provide the ultimate conclusive

[122] King v. Lufe, 103 ER 316

remedy to determine the paternity and maternity of the child, so that he can claim maintenance.

10. DNA and Right to Privacy/Information:

10.1 Concept of right to privacy

(a) What is meant by right to privacy?

necessitas publica major est quam private", Public necessity is superior to private. Therefore there has always the conflict between right to privacy and public interest in form of right to information

The term "privacy" is the rightful claim of an individual to determine to the extent to which to which he wishes to share of himself with others and his control over the time, place and the circumstances. It is individual's right to withdraw or participate as he sees fit. It also means an individual's right to control dissemination of the information about himself as such is his own personal possession.

(b) The Universal Declaration of Human Rights gives express recognition to right to privacy under Article - 12:

"No one shall be subject to arbitrary interference with his right to privacy, family, home or correspondence to attack upon his honour and reputation. Everyone has right to the protection of the law against such interference or attack."

(c) India is also a signatory to The International Convention on Civil and Political Rights, 1966.

Article 17 of the Convention reads as under:

1. No one shall be arbitrary or unlawful interference with his privacy, family or correspondence or lawful attack on his honour or reputation.
2. Everyone has right to protection of the law against such interference or attack.

(d) Article 8 Of the **European Convention on Human Rights** provides for: Right to respect for private life.

(e) Concept of right to privacy in United States -DNA testing and its application in legal system:

In U.S. the Constitution and the bill of rights establishes that mall the citizens are free to enjoy and exercise their basic liabilities except for limitation, which may be imposed due to exercise of the valid governmental power. The fourth Amendment provides them most direct protection of the right to privacy. The first elaborate discussion on right to privacy occurred in Boyd v. United State[123]. However the most well known cases on right to privacy are Grisword V. Connecticut[124] and Rove V. Wade[125]

(f) Concept of right to privacy in India:

The right to privacy has derived itself from essentially two sources, the common law of torts and Constitutional law. In common law, a private action for damages for an unlawful invention of privacy is maintainable.

In Kharak Singh V. State Of Uttar Pradesh[126] a question was raised whether right to privacy could be implied from the existing fundamental rights such as, Article-19 (1)(d) , 19(1) (c) and 21. The Supreme Court ruled, "Personal liberty is used as compendious term to include the varieties of rights, which make up the personal liberty of an individual other than those dealt with in Article 19(1).

In Govind V. State of M. P.[127] The Supreme Court accepted the right to privacy as an "emotion" from Article 19(1) and 21. The right to privacy is not however absolute. Reasonable restrictions can be placed upon the right in public interest under Article 19(5). In Rajgopal V. State of T.N.[128] The Supreme Court asserted that the right to privacy has acquired constitutional status; it is implicit ion the right to life and liberty guaranteed to the citizens under Article 21.

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[123] 116 U.S. 616 (1886)
[124] 381 U.S. 479 (1965)
[125] 410 U.S. 113 (1973)
[126] 1963 AIR 1295, 1964 SCR (1) 332
[127] 1996 (0) MPLJ 649
[128] 1995 AIR 264, 1994 SCC (6) 632

(g) The National Commission to review the working of the constitution has in its recommendations a new Article namely Article-21-B, should be inserted on the following lines.

21-B (1) Every person has a right to respect for his private and family life, his home and his correspondence.

(2) Nothing in Clause (1) shall prevent any state from making any law imposing reasonable restriction on the exercise of the right conferred by clause (1), in the interest of the security of the state, public safety or for the prevention of the disorder or the crime, for the protection of the health and morals, and for the protection of the rights and freedom of others.

The Judiciary and Legislation should strive to bring balance between the right to privacy and public interest with welfare of sate.

11. Genetic Privacy:

DNA sampling involves intrusion into three forms of individual privacy[129]:

Bodily privacy in cases where the sample is taken from a person's body;

Genetic privacy, where predictive health and other information about the person is obtained from the sample.

Behavioural privacy where the information is used to determine where a person has been and what he has done. Moreover, DNA sampling may also impinge on familial privacy where information obtained from one person's sample provides information regarding his or her relatives. Privacy and respect for human dignity need not be abandoned when balancing civil liberties with the larger interests of the community. Formulation of sound privacy principles can enhance the integrity and legitimacy of DNA profiling. The privacy principles with a statutory backing would bring about transparency and accountability and would reassure the community that what is

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129 See, "Essentially Yours: The Protection of Human Genetic Information in Australia", *ALRC Report 96* Available at http://www.alrc.gov.au/publications/39-forensic-uses-genetic-information/use-genetic-information (Last accessed on 2nd June, 2007)

sacrificed for greater safety and security is done so legitimately. In Australia, there is a comprehensive privacy law covering private sector.[130]

The power and potential of genetics rests in the knowledge it provides, thereby raising concerns about privacy and confidentiality in various situations. The personal information contained within the genetic tissue is more important than the tissue itself. The information gained from increased genetic knowledge will be of greatest interest to the affected individuals as well as to family members, employees, schools, insurers, medical and legal institutions. Genetic privacy would be an important constitutional issue arising in different contexts of individual's legal rights. The challenging task will be of striking a proper balance between privacy concerns and the fair use of genetic information.

Confidentiality even when carefully protected by researchers can be no substitute for an informed consent of individuals whose DNA sample is studied by researchers. Informed consent is seen as a strong and important way for individuals to exercise their privacy rights. The policy question for all authorities deliberating in the Gene Age is how to make laws which assure consumers of healthcare that their personal privacy is maintained and that their genetic information is not used against them, but at the same time, to encourage the advancement of genetic research for improving the standards of human health and the quality of life. An individual's genetic information and DNA sample are the property of an individual except when the information or sample is used in an anonymous research in which the identity of the person from whom the sample is collected cannot be determined.

Special privacy protections are needed to be developed by law because (i) genetic test results can be used to predict future health risks that might be of interest to insurers or employers, (ii) genetic test results apply to a whole family and therefore, are of interest to others, besides the individual patient, and (iii) information from a genetic test can be kept in many different places and under conditions over which an individual has no control.

A Genetic Privacy Act, therefore, should address to the following questions:

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[130] The Privacy Act, 1988 as amended by the Privacy Amendment (Private Sector) Act, 2000

- Who can collect genetic information?
- Who can retain genetic information, and how long?
- Who can disclose genetic information and under what conditions?
- There should be a privacy statute preventing any person from obtaining genetic information from any individual, or from an individuals DNA sample, without first obtaining informed consent of the individual or the individual's representative.

The statute may provide exceptions to the requirement or informed consent in the following circumstances:

(i) in the case of certain law enforcement and legal proceedings; (ii) for anonymous research; (iii) for identification of deceased individuals such as in mass disasters, due to earthquakes, flood furies or terrorist activities; (iv) for newborn screening procedures; (v) for the purpose of establishing patenting under court orders.

The genetic privacy statute should prohibit employers from obtaining, seeking to obtain or using genetic information to discriminate against or restrict any right or benefit otherwise due or available to an employee or a prospective employee and make it as unlawful employment practice for an employer to require an employee or prospective employee to take a genetic test. Procedures for obtaining informed consent should be specified. If health insurers ask an applicant to take a genetic test, they must obtain the authorization of the applicant for the test and they cannot use the results of the test to either induce or discriminate against the person in providing him or her with insurance.

In determining whether taking of body samples is justified in all circumstances the statute may cast a duty upon the police officer to balance the public interest in obtaining evidence tending to confirm or disprove that the suspect committed the offence concerned against the public interest in upholding the physical integrity of the suspect.

In balancing those interests, consideration of the following matters would be relevant:-

(i) the extent to which the suspect may have participated in the commission of the crime; (ii) the gravity of the offence and the circumstances in which it is committed; (iii) age, physical and mental health and cultural background of the suspect to the extent they are known; (iv) whether there is less intrusive and practical way of collecting evidence tending to confirm or disprove the involvement of the suspect in the crime; (v) the reasons, if any, for the suspect for refusing consent. A police officer may ask the suspect (other than a child or incapable person) to consent to a forensic procedure if he is satisfied on the balance of probabilities that: the person is a suspect, that there are reasonable grounds to believe that the obtaining of the DNA sample of the suspect is likely to produce evidence tending to confirm or disprove that the suspect committed a relevant offence, that the request for consent is justified in all the circumstances, and that the suspect is not a child or an incapable person. [131]

12. DNA Database and Constitutional Concerns:

In 1994, the DNA Identification Act authorized the FBI to establish the combined DNA Index System (CODIS), which consisted of three tiers of DNA data, namely, the Local DNA Index System (LDIS), which consisted of information installed by the laboratories of local police and sheriff departments; the State DNA Index System (SDIS) which allowed the individual local laboratories to exchange information throughout the state, and the National DNA Index System (NDIS) that allowed states to share information between each other on a national scale[132].

The Australian Law Reform Commission[133], in its report "Essentially Yours: The Protection of Human Genetic Information in Australia", in Chapter 43 relating to DNA Database Systems referred to the provisions for the usage, storage and disclosure of information of DNA database system contained in Part 1D of the Crimes

[131]Forensic Procedures can be devised on the lines of Part 1D of the Crimes Act, 1914 (Cth); See various legislations referred in paragraphs 39.17 to 39.58 – Part J "Forensic Uses of Genetic Information" of the Report of the ALRC – "Essentially Yours: The Protection of Human Genetic Information in Australia"; See also Oregon Genetic Privacy Act.

[132] See, Honourable Mr.Justice R.K.Abichandani, "The Gene Age – A Legal Perspective" ,Available at http://gujarathighcourt.nic.in/Articles/legalpers.htm (accessed on: 12th June, 2007)

[133] See, Australia. Law Reform Commission, National Health and Medical Research Council (Australia). Australian Health Ethics Committee "Essentially yours: the protection of human genetic information in Australia : report" *Australian Law Reform Commission, 2003* http://books.google.com/books/about/Essentially_yours.html?id=PnkLSwAACAAJ (accessed on: 25th June, 2007)

Act and noted that, as of February 2003, Commonwealth had established three DNA databases for law enforcement purpose; the National Criminal Investigation DNA Database (NCIDD System) was established in June 2001 to facilitate intra-jurisdictional matching of DNA profiles, and inter-jurisdictional matching of profiles between participating jurisdictions, for law enforcement purposes, the Disaster Victim Identification Database (DVI) was established in October 2002 to identify the victims of the terrorists bombings in Bali, Indonesia, and other similar overseas incidents, finally, the Australian Federal Police (AFP) operates its own DNA database for law enforcement purposes. The CrimTrac Agency operates the NCIDD system and the DVI database pursuant to part 1D of the Crimes Act, 1914. It is an executive agency of the Commonwealth Government, established as a national law enforcement information system for Australia's police services.

DNA database system as defined in Section 23YDAC of Part 1D of the Crimes Act 1914 (Cth) of Australia, means a database (whether in computerized or other form and however described) containing: (a) the following indexes of DNA profiles: (i) a crime scene index; (ii) a missing persons index; (iii) an unknown deceased persons index; (iv) a serious offenders index; (v) a volunteers (unlimited purposes) index; (vi) a volunteers (limited purposes) index; (vii) a suspects index; and information that may be used to identify the person from whose forensic material each DNA profile was derived; and (b) a statistical index; and (c) any other index prescribed by the regulations."

With the expansion of DNA databases, a concern has grown over privacy and abuse issues associated with such databases. The database supporters argue that statistics show that many offenders of particular types of crimes e.g. sex offenses, have a high incidence of repeat offenses, and a DNA database will help law enforcement identify suspects of new crimes who were previously convicted of earlier crimes. It is expected that DNA databases will produce a deterrent effect to counteract recidivistic tendencies and released convict will be less likely to commit crime again if he knows that his DNA is on file with the government and he can therefore be easily detected. The opponents of DNA databases, however, claim that such a course violated the society's commitment to reform, especially with respect to juvenile offenders, and the

presumption of innocence. They also fear that, with a centralized system, DNA data easily could get into the wrong hands.

The major concern that most database critics have is that DNA database sampling statutes allow for the mass screening of individuals without individualized suspicion or probable cause. The general justification given to support such sampling is the notion that a class of certain convicted felons is more likely to pose a danger to society than others. Critics claimed that such a justification undermined citizen's protection against unreasonable searches and seizures.

The issue arose in Donald E. Landry v. Attorney General[134] before the Massachusetts Supreme Judicial Court, whether involuntary taking of blood samples from the person in accordance with the provisions of the Act violated Fourth Amendment of the U.S. Constitution which protected the right of the people to be secured in their persons, houses, papers, and effects, against unreasonable searches and seizures, by providing that these shall not be violated and no warrants shall issue, except upon a probable cause, supported by oath or affirmation, and particularly describing the place to be searched, and the persons or things to be seized. The plaintiffs challenged the validity of a Massachusetts DNA database statute, which required involuntary collection of blood samples from all persons convicted of thirty-three different types of offenses. The given legislative purpose of the statute was to "assist local, state and federal criminal justice and law enforcement agencies in: (1) deterring and discovering crimes and recidivistic criminal activity; (2) identifying individuals for, and excluding individuals from, criminal investigation or prosecution; and (3) search for missing persons. The statute states and regulates the use of the database for primary criminal investigative purposes. The statute, however, also allows for the use of the database for other court proceedings and advancing other humanitarian purposes. The plaintiffs argued that the statute allowed for an unconstitutional search and seizure under both the Federal and State constitutions. The Massachusetts Superior Court agreed and issued a preliminary injunction against the statute. The Massachusetts Supreme Judicial Court however, disagreed with the lower court's reasoning and reversed the decision holding that the Act did not violate the Fourth Amendment. It was observed:

[134] SJC-07899 & 07916) 429 Mass. 366, 709 – NE2d 1085-(1999)

"There is no disagreement that the involuntary collection of a blood sample from a person designated to furnish one under the Act constitutes a "search and seizure" for purposes of the Fourth Amendment.

The premise for the above approach is that convicted persons unlike other citizens have a diminished expectation of privacy in their identity. Once a person is convicted of a serious crime, his identity becomes a matter of state interest and he loses any legitimate expectation of privacy in the identifying information derived from the blood sampling. The courts using this analysis go on to examine the reasonableness of the search and seizure, and they have all concluded that the intrusion occasioned by a blood test is "not significant", involving little risk or pain. The courts engage in a balancing test, weighing government's strong interest in preserving an identification record of convicted persons for resolving past and future crimes against the minor intrusion into their diminished privacy right in their identities by the taking of a DNA sample.[135] The other approach used to justify taking of blood from convicted persons for DNA identification analysis is based on existence of "special needs beyond law enforcement". In State v. Olives[136] search & seizure for DNA was justified on the ground that the government has "special need", "to prevent accidents and casualties in railroad operations that result from impairment of employees by alcohol or drugs". Under this analysis, the establishment of a DNA data bank is considered a deterrent to recidivism on the part of convicted persons, and therefore, suspicion less blood testing is justified because it serves a special need beyond "normal" law enforcement.

It is recognized that maintenance of fingerprint, photograph and arrest records serve an important law enforcement function. The arrest record serves as a means for identification and apprehension of criminals. The State has an established and indisputable interest in preserving a permanent identification record of convicted persons for resolving past and future crimes and uses fingerprints, and now will use DNA identification, for this recognized purpose. The balance of interest clearly weighs in favor of the use of DNA in accordance with the governing statute to create a record of identification. In Landry's case, the Court held that, "... While obtaining and analyzing the DNA under the Act is a search and seizure implicating Fourth

[135] Jones v. Murray, 962 F.2d 302, 307.
[136] 122 Wash.2d 73, 98(1993)

Amendment concerns, it is a reasonable search and seizure. This is so in light of a convicted person's diminished privacy rights. The minimal intrusion of Blood test and the legitimate government interest in the investigation and prosecution of unsolved and future criminal acts by the use of DNA in a manner not significantly different from the use of fingerprints.

In Robert Roe v. Ronald Marcotte[137], United States Court of Appeal for the Second Circuit, while considering the Public Act 94 – 246 of the Connecticut Legislature which provided that, any person who is convicted of a violation of the sections mentioned therein on or after October 1, 1994 and is sentenced to the custody of the Commissioner of Correction or has been convicted of a violation of the referenced sections and on October 1, 1994, is in the custody of the Commissioner of the Correction shall, prior to release from such custody, have a sample of his blood taken for DNA analysis to determine identification characteristics specific to the person; and further, any person convicted of a violation of the specified provisions on or after October 1, 1994, who is not sentenced to a term of confinement shall, as a condition of such sentence, have a sample of his blood taken for DNA analysis to determine identification characterizes specific to the person. The plaintiffs were subject to the provisions of the statute because of their conviction of sex offences, which were specified under the statute and their continued incarceration on or after October 1, 1994. The DNA statute was challenged as unconstitutional to the extent that it encompasses sexual offenders, whether or not their current imprisonment was predicated upon a sexual offence. The court concluded that a reasoned interpretation of "special needs" doctrine supports the constitutionality of the DNA statute. Dealing with the contention that the statute violated the equal protection clause because it impermissibly distinguishes between individuals convicted of crimes characterized as sexual offences and those convicted of other violent offences, the Court observed that the statute's alleged "under inconclusiveness" did not provide a basis for invalidating it, and that, under rational basis review, legislature may proceed "one step at a time". The Court held that the Statute did not violate the Equal Protection Clause.

[137] 410 U.S. 113 (1973)

The Supreme Court of State of Kansas in State of Kansas v. James E. Maass[138], in which James E.Maass appealed from the District Court's order requiring that specimens of his blood and saliva be submitted to the Kansas Bureau of Investigation, contending that the court lacked statutory authority to enter the order or, in the alternative, that the application of KSA 2001 SUPP. 21-2511 in his case was unconstitutional, held that the said provision did not constitute an unreasonable infringement upon the defendants' right of privacy or constitutional protection from an unreasonable search and seizure; and that, the District Court's order requiring blood and saliva specimens did not infringe upon Maass' right of privacy or constitute an unreasonable search and seizure. The Court held that the provisions were constitutional, as the minimally intrusive nature of providing blood and saliva samples was significantly outweighed by the State's interest in establishing and maintaining a state-wide automated DNA database to search, match and store DNA records.

In India, right of privacy has been culled out of the provisions of Article 21 of the Constitution and other provisions relating to the fundamental rights read with the Directive Principles of State policy. India is a signatory to the International Covenant of Civil and Political Rights, 1966. Referring to Article 17 of that Covenant and Article 12 of the Universal Declaration of the Human Rights, 1948, the Supreme Court in People's Union for Civil Liberties (PUCL) v. Union of India[139] it was held that, the right to privacy is a part of right to "life" and "personal liberty" enshrined under Article 21 of the Constitution, and it cannot be curtailed except according to the procedure established by law. In M. P. Sharma v. Satish Chandra,[140], it was observed that a power of search and seizure is in any system of jurisprudence an overriding power of the State for the protection of social security and that power is necessarily regulated by law. The Court observed that when the constitution-makers have thought fit not to subject such regulation to constitutional limitations by recognition of a fundamental right to privacy, analogous to the American Fourth Amendment, "we have no justification to import it into a totally different fundamental right, by some process of strained construction." Nor is it legitimate to assume that the statutory provisions for searches would defeat the constitutional protection under Article 20(3) (right against self-incrimination). However, the right to privacy was more specifically

[138] S.No.87, US, 918, March 7, 2003
[139] (1997) 1 SCC 301
[140] AIR 1954 SC 300

in issue in the context of disclosure of the outcome of the blood test in Mr. "X" v. Hospital Z[141], in which the appellant's blood sample was tested and he was found to be HIV positive which resulted in the appellant's proposed marriage being called off. The Supreme Court held that the right to privacy has been culled out of the provisions of Article 21 and other provisions of the Constitution. However, the right was not absolute and may be lawfully restricted for prevention of crime, disorder or protection of health or morals or protection of rights and freedom of others. It was held that, having regard to the fact that the appellant was found to be HIV (+), its disclosure would not be volatile of either the rule of confidentiality or the appellant's right of privacy as "A", whom the appellant was likely to marry, was saved in time by the disclosure, otherwise, she too would have been infected with the dreadful disease if the marriage had taken place and consummated. Once the law provides "venereal disease" as a ground for divorce to husband or wife, such a person who was suffering from that disease, even prior to the marriage cannot be said to have any right to marry so long as he is not fully cured of the disease.

Statutes such as Part 1D of the Crimes Act, 1914 (Cth) provide for establishing database system, offences in relation to the DNA database system, the protection of information stored in the DNA database system and the destruction of the forensic material. These provisions can be studied for devising similar provisions in respect of forensic procedures to be adopted for a database system in the Indian context.

13. Genetic Discrimination:

One ethical issue on the genetic horizon that has already begun to take focus is genetic discrimination. It is thought that, with the identification of all the genes in the human genomes that either condition or in some case cause disease accompanied by an availability of inexpensive methods of testing the genome of each individual, a person's individual genome would become part of a databank, one side of which would be proper medical care from birth to grave and even cure of genetically based diseases, while the other, the problems starting with insurability, and ending up in form of discrimination that for genetic reasons would prevent certain individuals from obtaining employment and, even medical services. Once the genetic disorders of

[141] (1998) 8 SCC 296

individual become known, it could justify higher premiums by the insurance company.

The greater the risk, higher the premium. Insurance may even be denied to those whose genes predict extended or expensive medical treatment. The existing state of computer linkage would make it difficult to prevent the movement of data from hospital to insurance carrier and to anyone else intending to find it out. One of the most important factors is the principle that genome information should not ultimately be restricted and the more we know, the better the health care plans can be. But this is contingent on whether we can have information without discrimination. The current structure seems to make it profitable for employers and insurance carriers to discriminate against individuals with certain genetic configurations, that is, it is in their best financial interest to limit or even deny health care. A restructuring is called for so that it becomes profitable to deliver, not withhold healthcare. To accomplish this, the whole nation will have to become more egalitarian – that is, to think of the nation itself as a single community willing to care for its own constituents.

14. The Human Genome Project, 1990 – 2003:

The Human Genome Project (HGP) traces its roots to an initiative in the U.S. Department of Energy (DOE). Since 1947, DOE and its predecessor agencies have been charged by the Congress with developing new energy resources and technologies and pursuing a deeper understanding of potential health and environmental risks posed by their production and use. In 1986, DOE took a bold step in announcing the Human Genome Initiative, convinced that its missions would be well served by a reference human genome sequence. Shortly thereafter, DOE joined with the National Institute of Health (NIH) to develop a plan for a joint HGP that officially began in 1990. During the early years of the HGP, the Welcome Trust, a private charitable institution in the United Kingdom, joined the effort as a major partner. Important contributions also came from other collaborators around the world, including Japan, France, Germany and China[142].

[142] See, "Genomics and Its Impact on Science and Society: The Human Genome Project and Beyond" Available at, http://www.voidspace.org.uk/technology/genome/2.shtml (accessed on: 21st July, 2007)

- The HGP's ultimate goal was to generate a high-quality reference DNA sequence for the human genome's 3 billion base pairs and to identify all human genes.
- Other important goals included sequencing the genomes of model organisms to interpret human DNA
- enhancing computational resources to support future research and commercial applications
- Exploring gene function through mouse-human comparisons, studying human variation, and training future scientists in genomics.

The powerful analytic technology and data arising from the HGP raise complex ethical and policy issues for individuals and society. These challenges include privacy, fairness in use and access of genomic information, reproductive and clinical issues, and commercialization. Programs that identify and address these implications have been an integral part of the HGP and have become a model for bioethics programs worldwide. In June 2000, to much excitement and fanfare, scientists announced the completion of the first working draft of the entire human genome. First analyses of the details appeared in the February 2001 issues of the journals Nature and Science. The high-quality reference sequence was completed in April 2003, marking the end of the Human Genome Project two years ahead of the original schedule. Coincidentally, this was also the 50th anniversary of Watson and Crick's publication of DNA structure that launched the era of molecular biology. Available to researchers worldwide, the human genome reference sequence provides a magnificent and unprecedented biological resource that will serve throughout the century as a basis for research and discovery and, ultimately, myriad practical applications. The sequence already is having an impact on finding genes associated with human disease. Hundreds of other genome sequence projects – on microbes, plants and animals – have been completed since the inception of the HGP, and these data now enable detailed comparisons among organisms, including humans.

Beyond sequencing, growing areas of research focus on identifying important elements in the DNA sequence responsible for regulating cellular functions and providing the basis of human variation. Perhaps the most daunting challenging is to begin to understand how all the "parts" of cells – genes, proteins, and many other

molecules – work together to create complex living organisms. Future analyses on this treasury of data will provide a deeper and more comprehensive understanding of the molecular processes underlying life and will have an enduring and profound impact on how we view our own place in it.

15. Protection of Human Genetic Information[143]

The Australian Law Reforms Commission recently published the results of the inquiry conducted jointly with NHMRC's Australian Health Ethics Committee, "Essentially Yours: The Protection of Human Genetic Information in Australia, a two volume, 12,00 page report, containing 144 recommendations about how to deal with ethical, legal and social implications of the "New Genetics". The report covers a wide range of areas, including human genetic research and genetic databases, genetic privacy and discrimination, and regulating the use of genetic testing and information in employment, insurance, immigration, parentage testing, sport and other contexts[144]. The report has been described as "an extraordinary accomplishment", providing a "world -leading platform for policy development". It is a comprehensive and instrumental report producing a number of welcome recommendations. The following are the main recommendations made by the A.L.R.C. Final Report[145]:

(i) The establishment of a standing Human Genetics Commission of Australia (*HGCA*) to provide high-level, technical and strategic advice about current and emerging issues in human genetics, as well as providing a consultative mechanism for the development of policy statements and national guidelines in this area.

(ii) Discrimination laws should be amended to prohibit discrimination based on a person's real or perceived genetic status.

(iii) Privacy laws should be harmonized and tailored to address the particular challenges of human genetic information, including extending protection to genetic samples, and acknowledging the familial dimension of genetic information. For example, doctors might be authorized to disclose confidential information to a genetic

[143]See, ALRC Discussion Paper 66 "Protection of Human Genetic Information", Available at www.austlii.edu.au/au/other/alrc/publications/dp/66/(Last Accessed on 15th July 2007)
[144] Ibid 132
[145] Ibid 132 and also see

relative where it is necessary to avert a serious threat to an individual's life, health, or safety.

(iv) Ethical oversight of genetic research should be strengthened by: ensuring that all genetic research complies with National Health and Medical Research Council, (NHMRC) Standards; better supporting Human Research Ethics Committees; providing more guidance to researchers and research participants about best practice; developing new rules to govern the operation of human genetic research databases; and tightening reporting requirements.

(v) Employers should not be permitted to collect or use genetic information except in those rare circumstances where this is permitted under anti-discrimination laws or is necessary to protect the health and safety of workers or third parties, and the action complies with stringent HGCA standards.

(vi) The insurance industry should be required to adopt a range of improved consumer protection policies and practices with respect to its use of genetic information (including family history) for underwriting purposes. New laws and practices should ensure that: genetic information is only used in a scientifically reliable and actuarially sound manner; reasons are provided for any unfavorable underwriting decision; industry complaints-handling processes are strengthened and extended to cover underwriting decisions; and industry education and training about genetics are improved.

(vii) A new criminal offence should be created to prohibit someone submitting another person's sample for genetic testing knowing that this is done without consent or other lawful authority (e.g. a court order, or the statutory authority given to police officers).

(viii) Lack of harmonization is threatening the effectiveness of any national approach to sharing DNA information for law enforcement purposes. The governments should develop national minimum standards for the collection, use, storage, destruction and matching of DNA samples and profiles. No inter-jurisdictional sharing of information should be permitted except in accordance with these minimum standards

(ix) DNA parentage testing should be conducted only with the consent of each person sampled, or pursuant to a court order. Where a child is unable to make an informed decision, testing should proceed only with the consent of either parents, or a court order.

16. Human Enhancement:

The most controversial issue regarding biotechnology is the prospect of employing it for the purpose of human enhancement. The distinction between enhancement and therapy is linked to the distinction between health and disease. A therapeutic modification is one that brings a trait that was below a recognizable, species-wide norm up to that norm. The term "trait" is meant, in its broadest sense, to include physical attributes, mental or physical abilities, dispositions, and capabilities. While it is true that therapeutic modifications attempt to treat disease whereas enhancement modifications attempt to improve a trait that is not diseased, there can be considerable debate over whether a particular modification constitutes an enhancement and why. Ethical issues regarding enhancement modification should then be seen in terms of the ethics of medicine and the professional duties and responsibilities of health professionals. There are modifications that, strictly speaking, are enhancements, but whose purpose is to respond to the threat of a disease. For example, a modification that improves people's resistance to particular diseases beyond the normal capacity would count as an enhancement but its purpose would be disease prevention and so arguably therapeutic. There could be modifications that raise a trait from one point within the normal range of that trait to a higher point in that range.

This suggests that the classification of modifications should be tripartite: therapeutic, (proper) enhancement, and intra-normal. Cosmetic surgeries, which can often be regarded as intra-normal modifications, are thus placed in the same category as genetic modifications to create super people. Biotechnology covers a range of technologies and procedures, many of which could conceivably be employed for enhancement. Drugs could be designed to interact with the body's chemistry in such a way as to alter behavior, biological functioning, structure, or affect them. Even without introducing drugs, special procedures – such as transfusing persons with their own blood or "blood doping" – can affect traits or behavior. But the most discussed enhancement technology is one in which a person's genome is altered. While a

popular image of genetic enhancements is that of some magic-wand transformation in which the person is a passive recipient, the matter can be more complex. The object of a somatic modification is a modified individual, but the object of a germ line modification is a modification that becomes part of the individual's legacy or inheritance. Somatic enhancements are simpler as far as ethics and public policy is concerned. It is considered that using biotechnology to effect an improvement is wrong because it is artificial. There is also a concern that, using biotechnology in order to effect an improvement undermines the value of the improvement. The value we place on certain achievements may depend upon the struggle and effort required to achieve them. If they could be made effortless – at least on the part of the individual – and common, we might well cease to value them. It is also suggested that, using biotechnology to enhance people is not the sort of thing physicians should do because the values or aims of the medical profession are held to be incompatible with performing enhancements. This view however leaves ethics of enhancements untouched.[146]

17. Genetic Weapons:

Scientists have warned that recent advances in biological research could eventually lead to the creation of a new type of biological arsenal capable of targeting a specific group of human beings with common genetic characteristics, as may be the case with certain ethnic groups.It will unfortunately be possible to design biological weapons of this type when more information on genome research is available Report", which he wrote for the BMA, examined the questions of how the revolution in biotechnology might be used to attack the genetic constitution of an ethnic group. The world community is already struggling to eliminate existing biological weapons, which carry agents spreading deadly diseases like anthrax and other lethal toxins, and can devastate human beings without causing damage to buildings or infrastructure[147]. A few hundred kilograms of a "weapon zed" bacterial preparation has the potential to wipe out up to three million inhabitants concentrated in a city like New York. In the

[146] See, Robert Wachbroit, "Human Enhancement Uses of Biotechnology":Encyclopedia of Ethical, Legal and Policy Issues in Biotechnology, Wiley Reference Works "Biotechnology,Weapons and Humanity" ,Available at http://onlinelibrary.wiley.com/doi/10.1002/0471250597.mur098/full and also see http://findarticles.com/p/articles/mi_m1310/is_1999_March/ai_54311680/ (Last accessed on: 13th August, 2007)

[147] http://gujarathighcourt.nic.in/Articles/legalpers.htm (Last accessed on 15th September, 2007)

past, however, countries have rarely used such biological weapons in warfare, because of their fear of eliminating friendly populations and killing their own combatants. The problem of the proliferation of biological weapon research has been aggravated by fall-out from the collapse of the former Soviet Union. Most of the nearly 30,000 scientists who were involved in biological research in the USSR during the 1980s were out of job because of the country's economic difficulties. Such scientists could be engaged by terrorists or cult groups for acquiring biological weapons which may be used by them irresponsibly having regard to the nature of their goals. The professional scientists and physicians should shoulder their ethical responsibilities and take no part in biological and genetic weapon projects. There is also a growing concern about the misuse of genetic information available on Internet. Scientists worldwide share information on new findings in biological research through Internet, which could be manipulated by private groups. Internet service providers are under an ethical obligation to ensure that information on biological weapons is not made available on their websites[148].

The spectre of new biological weapons made possible by the mapping of the human genome makes it more urgent than ever to prevent biotechnology research from being hijacked. It sounds like science fiction, but like many another prediction that was once dismissed. As far-fetched it may become a reality.

Scientists have warned that recent advances in biological research could eventually lead to the creation of a new type of biological arsenal capable of targeting a specific group of human beings with common genetic characteristics, as may be the case with certain ethnic groups. "It will unfortunately be possible to design biological weapons of this type when more information on genome research is available," says Dr Vivienne Nathanson, head of science and health policy at the British Medical Association (BMA), the body which represents the medical profession in the United Kingdom.

This terrifying prospect may be an unwelcome piece of spin-off from research being carried out under the Human Genome Project (see box), an international scientific effort to map and sequence the genes in the human body and find out more about

[148]See, Ethirajan Abrasion, "Genetic Weapons: A Twenty-First Century Nightmare", , Kamal Book House, 2006, Available at http://www.mail-archive.com/ctrl@listserv.aol.com/msg74311.html

human DNA (deoxyribonucleic acid), the molecule which provides the biological instructions to make a human being.

Repairing defective genes

The genome research achieved a breakthrough when scientists for the first time deciphered the full genetic programming of an animal. The creature was a microscopic roundworm known as Caenorhabditis elegans, but because worms and humans have turned out to share many genes in common, the worm genome is regarded by biologists as an essential basis for understanding how the human genome works.

Scientists say a detailed understanding of genetic mechanisms of human beings will help them to find out the causes of many diseases. For example, knowledge of an individual's genetic make-up will enable doctors to predict whether or not a specific drug will work on a particular patient, allowing therapies to be more accurately targeted. Similarly, genetic testing for predisposition to a range of illnesses could become feasible, and by using what is known as gene therapy doctors would be able to replace deficient genes or repair defective ones.

However, genome research may turn out to have a grim downside. It has proved that biologically there are more similarities between human beings than differences, further dissolving traditional prejudices of race and ethnicity. However, differences do exist, and if investigations provide sufficient data about ethnic genetic differences between population groups, it may one day be possible to target the groups with dangerous micro-organisms.

The apartheid regime in South Africa is widely believed to have developed forms of biological weaponry for use against the black population. In the past, however, countries have rarely used such biological weapons in warfare, partly because of their fear of eliminating friendly populations and killing their own combatants. The new developments in genetic research described by Professor Dando would remove these limitations.

Genetic information is already being used in some countries to "improve" biological weapons, e.g. by equipping them with agents to provide increased antibiotic

resistance–and it is likely that this trend will accelerate as the knowledge and understanding of its applications become more widely known.

The problem of the proliferation of biological weapon research has been aggravated by fall-out from the collapse of the former Soviet Union. Most of the nearly 30,000 scientists who were involved in biological research in the USSR during the 1980s are now out of a job because of the country's economic difficulties. Last year, some of them disclosed that they had been approached by certain countries which have shown particular interest in learning about microbes that can be used in war to destroy or protect crops, as well as genetic engineering techniques that could be used to make deadly germs for which there may be no antidotes.

The scientists in countries that belonged to the former Soviet Union should be diverted from involvement in programmes with sinister motives by schemes such as scientist-to-scientist exchanges, joint research projects and the conversion to civilian use of laboratories and institutes once associated with the Soviet military effort. One prospect that alarms arms control experts is that biological weapons will fall into the hands of terrorist or cult groups. Twelve people were killed and 5,000 injured in the Tokyo subway in 1995 in an attack launched by the Aum Shinrykyo cult using sarin, a lethal nerve gas that produces asphyxia. Investigations later revealed that the cult group had had no problem in recruiting scientists to work on biological weapons but could not employ the weapons due to lack of a proper delivery system.

As a first step in coping with the problem of potential new biological weapons, arms control experts are calling for the bolstering of the Biological and Toxin Weapons Convention (BTWC), an international treaty signed in 1972. The convention prohibits its signatories from developing, producing, stockpiling and acquiring biological weapons.

though 142 nations have signed the convention so far, this has not deterred countries from developing or obtaining knowledge on biological weapons. "This is mainly because there is no verification system attached to the convention," he says.

Monitoring the uses of genome mapping

"The threat of new genetic weapons is clearly going to be an ongoing problem for the international community. Such weapons are covered by the current treaty, but this needs to be strengthened by an effective verification protocol and fully implemented so we can be sure states comply with their obligations. A variety of tools should be used, including arms control, export controls and enhanced intelligence capability to monitor countries of concern.

The BMA report cited earlier says professional scientists and physicians should shoulder their ethical responsibilities and take no part in biological and genetic weapon projects. It calls for close monitoring of developments in biotechnology worldwide and open debate, particularly in relation to the use of genome mapping. However, These measures can minimize the threats but not eliminate them

There is also growing concern about the misuse of genetic information available on Internet. Scientists worldwide share information on new findings in biological research through Internet which could be manipulated by private groups .Internet service providers have an ethical obligation to ensure information on biological weapons is not available on their websites.

One big problem in monitoring is how to distinguish between research carried out for good and evil ends. The fact is that genetic research which develops specific therapeutic agents is scientifically indistinguishable from research to develop a lethal or disabling agent targeted at specific clusters of genes in an ethnic group. This makes it all the more necessary to make sure that information is used for positive purposes. One avenue to be explored is to ensure that developing countries are given the opportunity to share the benefits of the modern revolution in biotechnologies which can be used for disease control and economic development. In return they would be required to promise that malign research would not be carried out in their laboratories. "This is currently being negotiated by countries which are party to the BTWC," he says.

18. Gene Patents

Introduction

18.1 Background to biotechnology and Intellectual Property -

Since the discovery of Recombinant DNA technology in the early 1970's, Biotechnology has become an important tool for many researchers and industries. Biotechnology and the inventions arising out of it have many inventors and have played an important role in improving the health, food supply and environment. Turning Biotechnology inventions into protected Intellectual Property, with concomitant Intellectual Property Rights have been taking place for over a century.

For example, Louis Pasteur was granted a French patent in 1865 for yeast clones that he isolated from mixtures of yeast species. The application of technology to agriculture has helped contribute enormous increases in yield and quality. The isolation of adrenalin over a century ago from the human suprarenal gland was an important advance in the field of medicine. Rapid developments in biotechnology during the past decade have enabled corporations, scientists and "bio prospectors" to alter nature's handiwork for commercial profit. A major strategy for private exploitation in this area is to obtain the patent rights to an organism or its component parts. As these developments affect all of society, we need to decide whether any corporation, institution, or individual should have the right to private ownership of life.

The society has been benefited a lot from patent inventions, but the question is whether the application of the patent system to DNA sequences is achieving its goals, namely using innovation for the public good, and the rewarding of people for useful new inventions. We know that many patents that assert rights over DNA sequences have already been granted but are of doubtful validity. The effects of many of these patents are extensive as well as controversial, because inventors who assert rights over DNA sequences obtain protection on all uses of the sequences which has generated a lot of controversy as they directly come into conflict with many moral and

ethical questions. In the light of this controversy we have attempted to examine various aspects relating to DNA patenting[149].

18.2 How the Patent system works:

Meaning: Before turning to the question of patents involving genes, it is important to discuss the patent system in general.

Patents are exclusive rights granted for a limited period of time by states through their legal systems to inventors to prevent others from exploiting the patent holder's invention. Patent applications contain claims which set out the precise nature of the protection.

The patent claims are drafted to avoid the exact duplication of the the inventor's work Patents can be broadly divided into three categories, though these categories are not formally distinguished under the patent system.

i. A product patent is a patent on the product itself. The term 'product' normally means a mechanical, chemical or biological entity, substance or composition (as distinct from a device or electrical circuit). A patent that asserts rights over a product itself covers all uses of that product.

ii. A process patent is a patent on a method or process. This covers a process, and may also include what is directly produced from the process. If a product is made by another process, not covered by the patent, it does not infringe it. A use patent is a patent on the use of the product for a specific purpose; only the specified use is covered.

An important feature of product patents is that they extend to new uses of the invention that may develop subsequently, even if these uses were not anticipated or predicted by the owner of the patent.

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[149]Carsten Fink, How Stronger Patent Protection in India Might Affect the Behavior or Transnational Pharmaceutical Industries, Development Research Group The World Bank Oliver Mills, Biotechnological Inventions: Moral Restraints and Patent Law, *Ashgate Publishing, Ltd*, (2005) 170 I 447U.S.303, 206 USPQ 193 (1980) and See also 2004 SCC 34.
Swiss Federal Institute of Intellectual Property, Research and Patenting in Biotechnology-a Survey in Switzerland.WIPO Academy notes.Property and Bioethics- An Overview, Consultation Draft WIPO Margaret Sampson, The Evolution of the Enablement and Written Description Requirements under 35 U.S.C. §112 in the area of Biotechnology, 15 BerkeleyTech.L. J. 1233, 1234 (2000).
Bioethics and Patent law – The Relaxin case, *WIPO Magazine*, April 2006.

Of the three main kinds of patent i.e. product, process and use patents, *only product patents can assert rights over DNA sequences themselves.* Use patents only extend to the use of the sequence. In practice, use patents may also restrict access to the DNA sequence itself.

18.3 Gene patenting:

Genetic Science and related technologies are important in medical research and in the development and provision of healthcare, and, their significance for human health is likely to increase as more becomes known about the biological functions of genes and the proteins they produce.

Human genetic research aims to enhance understanding of how genes and environmental factors operate and interact to influence the health of individuals and populations – and in so doing, to generate knowledge with the potential to improve individual and community health. Human genetic research may translate into the development and provision of new forms of healthcare involving, among other things, medical genetic testing, pharmacokinetics, gene therapy, and the use of therapeutic proteins or stem cells. There are many ways in which the potential subject matter of gene patents might usefully be categorized.

The potential subject matter of gene patents can be grouped into the following four broad categories:-

i. Genetic technologies – The methods and items used in genetic research and genetics – based healthcare, including those used in sequencing DNA, medical genetic testing, other diagnostic uses and gene therapy;
ii. Natural genetic materials – Forms of genetic material in their natural state, including DNA, RNA, genes and chromosomes;
iii. Isolated genetic materials – Forms of genetic material isolated from nature, including genetic materials of whole genomes, gene fragments.

iv. Genetic products – Item produced by the use of genetic materials, including proteins, nucleic acid probes, nucleic acid constructs such as vectors and plasmids, and anti-sense DNA.[150]

Patenting of new and improved genetic technologies would ordinarily be the least controversial area of gene patenting, since the issues of "invention", "novelty" and "usefulness" is clearer than they are in case of patents over genetic materials. There is a distinction between a gene or a gene fragment.i.e. in the human body or another organism and a gene or gene fragment that has been extracted from the body by a process of isolation and purification. In general, raw products of nature are not patentable. DNA products usually become patentable when they have been isolated, purified, or modified to produce a unique form not found in nature.[151]

Isolated genetic material will be patentable, genetic materials in their natural state usually are not. Natural genetic materials include genetic materials in living cells, such as, stem cells. Claims must be formulated so as to clearly distinguish what is claimed to be patented from the naturally occurring molecule. While naturally occurring (e.g. as embryonic stem cells), stem cells may be patentable when isolated and propagated to produce a "cell line". Genetic materials include living cells that have been modified by genetic manipulation – such as, in gene therapy. The Human Genome Project has noted that therapeutic cloning, also called "embryo cloning" or "cloning for biomedical research" is the production of human embryos for use in research. The goal of this process is not to create cloned human beings but rather to harvest stem cells that can be used to study human development and treat disease. Stem cells are important to biomedical researchers because they can be used to generate virtually any type of specialized cell in the human body". [152]

The question as to whether a live human – made micro – organism is patentable subject matter under the U.S. law, Title 35 U.S.C, 101, which provided for the issuance of a patent to a person who invents or discovers "any" new and useful "manufacture" or "composition of matter" within the meaning of that statute arose before the U.S. Supreme court in Diamond v. Chakrabarty, The Supreme Court found

[150] See ALRC Issue Paper 27, Intellectual Property Rights over Genetic Materials
[151] See Human Genome Project, "Patenting Genes, Gene Fragments, SNPs, Gene Test, Proteins and Stem Cells, U.S. Department of Energy", 17th June 2003).
[152] See Human Genome Project, "Patenting Genes, Gene Fragments ..." U.S. Dept. of Energy

that the patentee had "produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility". It was held that, "His discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter," under Title 35 U.S.C. 101.

The Supreme Court noted that Chakrabarty's patent claims were of three types:

First, process claims for the method of producing bacteria;

Second, claims for inoculums comprised of a carrier material floating on water, such as straw, and the new bacteria;

Third, claims to the bacteria themselves.

The patent examiner allowed the claims falling into the first two categories, but rejected claims for the bacteria, on two grounds: (i) that micro-organisms are "products of nature", and (ii) that as living things they are not patentable subject matter under 35 U.S.C. 101. The invention was claimed to be human-made, genetically engineered bacterium, capable of breaking down multiple components of crude oil. Because of this property, which was possessed by no naturally occurring bacteria, Chakrabarty's invention was believed to have significant value for the treatment of oil spills. By breaking down multiple components of oil, Chakrabarty's microorganism promised more efficient and rapid oil-spill control. (Oil decomposed into simpler substances can serve as food for aquatic life). When the Supreme Court was pointed out the grave risks that may be generated by such research endeavors, the Court observed that, the briefs presented "a gruesome parade of horrible", and it was told that, genetic research and related technological developments may spread pollution and disease, that it may result in a loss of genetic diversity, and that, its practice may tend to depreciate the value of human life.

The Supreme Court observed that these arguments passionately presented reminded the court that, at times, human ingenuity seems unable to control fully the forces it creates – "that, with Hamlet, it is sometimes better "to bear those ills we have than fly to others that we know not of". The Court disagreed, and observed that the grant or denial of patents on microorganisms was not likely to put an end to genetic research

or to its attendant risks. "The large amount of research that has already occurred when no researcher had sure knowledge that patent protection would be available suggests that legislative or judicial fiat as to patentability will not deter the scientific mind from probing into the unknown any more than Canute could command the tides. Whether respondent's claims are patentable may determine whether research efforts are accelerated by the hope of reward or slowed by want of incentives, but that is all". The Court observed that it was without competence to entertain these arguments either to brush them aside as fantasies generated by fear of the unknown, or to act on them, and that the matter was of high policy for resolution within the legislative process which involves balancing of competing values and interests, that, in a democratic system, was the business of elected representatives.

Our Genes define us, as a species as well as individuals, and hence for human genes there are strong oppositions both on the religious and secular front. Patents are being granted to genes despite there being many arguments for keeping the genes in the public domain. A patent cannot be granted on a gene as it naturally occurs. Isolation of the gene is required for it to be patentable. The patent offices have treated genes as a new chemical compound and have granted "composition of matter" patents. Thus a patent granted on an isolated and purified DNA composition confers the right to exclude others from any method of using that DNA composition for upto 20 years from the date of filing. However Human Beings are not patentable as human multicellular living organisms are not a patentable subject matter under section 101.

18.4 Why are genes being patented[153]?

Genes have been used for gene therapy though it is still in the early developmental stages. The technology used in each gene therapy will have huge commercial value in the coming future making patenting crucial. However gene therapy is not a patentable subject matter in India.

Some of the genes encode proteins that can act as therapeutic agents. (e.g.; the human growth hormone). Hence by offering patent protection to such genes, the interests of the pharmaceutical industries will be maintained. However, the pharmaceutical

[153]See, Issues and controversies in Patenting Recent Biotechnological Inventions – Is the patenting of life equivalent to owning it?, Available at http://www.legalserviceindia.com/article/l254-Patenting-Recent-Biotechnological-Inventions.html(last Accessed on 10th August 2007)

industries should be granted access to the genes and not the ownership. Monopolies on genes are not in public interest.

For Biotechnological companies, gene patents are considered as value generators and enhance the value of the company in the eyes of the investors. Most of the Biotechnological companies and research institutes have created Technology Transfer Offices (TTO) so that the patents generated by their research will generate huge financial rewards.

Sequences of genes and genomics provide data for further research. The patenting of genes forces the disclosure of information instead of it being kept as a trade secret. Full and free access to genomics data is essential for academic research and owning gene patents are the best way to ensure hindrance free access to such data.

Some glaring questions relating the Patentability of genes

There is a current debate on the inherent dangers of the process of creating transgenic organisms, which is why UK and many countries in Europe are banning transgenic crops or imposing a moratorium.

Transgenic DNA has the potential to generate new viruses and bacteria that cause diseases, and may also cause cancer by integrating into mammalian cells. The transgenic DNA from terminator or GURT technologies involve even greater risks, as they contain dangerous genes that prevent germination, which can nonetheless escape into other species. Furthermore, the technologies depend on gene-splicings that have to be engineered and regulated very precisely, but those requirements are beyond the capability of the genetic engineer. The hazards of the transgenic DNA resulting from GURT technologies are much greater, because the imprecisions of inserting multiple gene-constructs are multiplied, and because of the gene-splicing sequences and genes deliberately introduced. Gene splicing has the potential to create new combinations of genes and to scramble genes and genomes when it is imprecise.

How can we regard this as a patentable invention when it is so hit or miss and unreliable? It is both scientifically flawed and ethically unacceptable to create so much suffering.

The patentability of genes and other nucleic acid sequences is justified on the ground that they have been subject to a microbiological or nonbiological process, i.e, gene sequencing, which is itself a standard process patentable and patented under existing patent laws for invention. So, the actual patented entity is the nucleic acid sequence itself and its putative function.

However, the DNA or RNA sequence is subject to change by mutation, deletion, insertion and rearrangement. Thus, the patent for the gene and the patent for the gene variant will legally clash. The same arguments of mutability of entire genomes raise the question as to which genome is being patented. If the patent is on one DNA base sequence, does it cover genomes differing in DNA base sequence?

18.5 Legal protection given to biotechnology:

Patents are viewed as vital to protecting the commercial interests and intellectual property rights in biotechnology. Patents are limited rights based on a claim that a new technological invention has been created and fully communicated to the public. Patents can cover new products, processes that creates these new products, new processes for producing existing products and new processes generally. While patenting of a biotechnological invention it is important that it meets the 3 criteria's laid down by the TRIPs to meet patentability, namely which are new or novel, involves an inventive step or not obvious and capable of industrial application. The TRIPs gives the option of excluding certain forms of subject matter from patentability.

1. Diagnostic and surgical methods for the treatment of humans or animals.
2. Plants and animals other than micro-organism and biological processes for the production of plants or animals other than non-biological and micro-biological processes.

However the patenting of new life forms raises arguments in favor of and against the issuance of such patents. Most recently, public debate has centered on the patenting of animals. Discussions regarding the patenting of a genetically engineered organism can involve questions relating to the environmental application of the organism, scientific questions, ethical issues and economic considerations.

The other forms of IP Protection that can be offered to biotechnology involve *plant breeder's rights, trademarks, trade secrets and geographical indications.*

Extent of protection offered by patents-some legal and technical Concern - The protection conferred by a patent on a biological material extends to any biological material derived from that biotechnologically invented material through propagation or multiplication and possessing the same characteristics. The protection conferred by a patent on a product containing the genetic information extends to all material in which the product is incorporated.

However the protection does not extend to plant-propagating material or breeding stock sold to a farmer by the holder of the patent or with his consent, provided that the farmer uses the biological material or livestock for his own agricultural purposes.

Where a breeder cannot acquire or exploit a plant variety right without infringing a prior patent, he can apply for a compulsory license for non-exclusive use of the invention protected by this patent, subject to payment of royalty.

Biotechnology is special and it is based on living organisms[154]. Indeed, biotechnological inventions can be self-reproducing and self disseminating. The Biotechnology Industry Association (BIA), the representative body of international biotech product makers in a representation to the office of the US Trade Representative (USTR) on February 2008 contented that each patent applicant is responsible for tracing the history of all naturally-derived biological materials contributing to the invention, even if the applicant obtained the material from a commercial supplier and the material has been available from secondary sources for decades. The failure to identify the geographical source of a biological material used in the invention may be the basis for opposition or revocation proceedings. Such requirements pose unacceptable risks for patent applicants and would undermine the incentives of the patent system to promote innovation in biotechnological inventions.

The application of the patent system in the field of biotechnology and biomedicine is justifiable as a way of striking a reasonable balance between the right of inventors and

[154]See, Article on Patents, Available at http://www.docstoc.com/docs/22615485/patent(Last Accessed on 20yh August 2007)

the public interest. But such patents involve some legal and technical issues which are as follow:

a. Should not be allowed special status

The first concern is that patents which assert right over DNA sequences in particular human DNA sequences should not be allowed by virtue of the special status or nature of DNA. While dealing with this question we have to draw an important distinction between the acquisition of knowledge about the nature and functions of a DNA sequence, and the information contained within that sequence. Although we think that the judgment that isolated DNA sequences are eligible for patenting, is based on questionable extrapolation to the case of genetic information from the case of the isolation of chemical compounds, we accept that a limited number of the early patents granted on that basis need not now be called into question in view of the inventiveness required to isolate the DNA sequences. Since the early days of the pioneering experiments using positional cloning techniques patents have been field on many DNA sequences, which were mass-produced by a mixture of computational and cloning techniques. Even if it can be convincingly argued that these sequences were eligible for patenting, the patents should be examined in the light of the criteria for inventiveness and utility. We note that as a technique have advanced, and in particulars as the use of computers to identify genes has become more widespread the eligibility of DNA sequences for patenting should have diminished.

b. Patents not meeting legal criteria should not asserts rights over DNA sequences

The second concern is that patents which assert rights over DNA sequences should not be allowed because they do not meet the legal criteria for patenting. With regard to the legal criteria for assessing patents with claims to DNA sequences, while the test of novelty can be met, the tests of inventiveness and utility are more problematic. In the case of inventiveness, we hold that as the use of computational databases becomes the standard way of identifying genes, it is difficult to see how the test can be met, despite current US practice. In the case of utility, we argue that the standard of credibility required for a claimed utility needs to be set higher than the mere

theoretical possibility of this utility; some positive evidence that the DNA sequence has the claimed utility should be required.

Patenting of Micro-organisms and Cells – The first successful directed insertion of recombinant DNA into a host micro-organism took place in 1973, and since then scientists realized the huge potential involved in directing cellular machinery to develop new and improved products and processes. Many of these products were micro-organisms or cells. Hence with the development of the recombinant DNA technology, the potential of patenting the living organism resulting from the technology arose[155].

Post Chakrabarty trends- The Chakrabarty decisions and the subsequent actions enacted by the US congress provided great economic stimulus to the patenting of micro-organisms and cells, and in turn provided stimulus to the growth of the biotechnological industry in the 1980's. However, increased patenting of biotechnological inventions has led to litigation related to patent infringement issues. The patent litigation is only likely to increase in future considering the overlapping of patent claims, the high value of products, problem of prior publication and the fact that many companies are pursuing the same product. The increase in the patent claims leads to the inability of the patent offices to process the biotechnological inventions in a timely manner. Turnover amongst the patent examiners, luring them to the private sectors by offering higher pay etc are reasons for the delay in the reviewing of patents[156]

Supreme Court of Canada in Monsanto Canada Inc. v. Schmeiser has laid down that higher life forms were not patentable because they were not a manufacture or composition of matter within the meaning of invention of the Patent Act.

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[155] In 1980, in the Diamond v. Chakrabarty ruling, the Supreme Court of US ruled that a living micro organism could be patented. Chakrabarty had developed a genetically modified bacterium capable of breaking down the multiple components of crude oil. Since this property was not possessed by any naturally occurring bacteria, the invention was thought to have significant value. It was held that a non-naturally occurring manufacture was a product of human ingenuity. DNA compounds having naturally occurring sequences are eligible for patenting when isolated from their natural state and when it meets the Hence by a 5-4 ruling it was held that a live, human made micro-organism is a patentable subject matter under section 101 as a "manufacture" or "composition". The fact that biotechnology was not predicted as a branch of science when the congress enacted section 101 does not arrive at the conclusion that micro-organisms are not a patentable subject matter until the congress expressly authorizes such protection

[156] See, Article on Patents, available at http://www.legalserviceindia.com/article/l254-Patenting-Recent-Biotechnological-Inventions.html(Last accessed on 2nd October 2007)

18.6 Patenting of Transgenic Animals –

The first animal patent was issued in April, 1988 to Harvard University for a particular type of mammal, namely the Harvard oncomouse, genetically engineered to obtain a cancer- causing gene. The oncomouse has been genetically engineered to carry a particular type of gene called as the oncogene which makes it susceptible to cancer and hence makes it ideal for cancer research. Subsequently the USPTO announced that it would consider non-naturally occurring non-human, multi-cellular organisms, including animals to be patentable subject matter under its laws.

Most of the animal patents have been granted to transgenic animals produced by recombinant DNA or genetic engineering. Negative impacts of patenting of transgenic animals- The major concern that arises out of patenting of transgenic animals are that transferring genes from one species to another transgresses the natural barriers between them and affects the integrity of species. Species belonging to the same group, though they may slightly vary from one region to the other based on the environmental conditions, they primarily have the same gene pool. By allowing patenting of transgenic animals, the fundamental genetic architecture is being tampered with.

a. Ethical-Moral Issues-

A number of ethical issues stem from the patenting of animals. Most of them deal with the consequences that could arise subsequent to patenting of animals while the other arguments focus on the religious, philosophical and spiritual grounds. The arguments which go against the patenting of animals are difficult to prove as many of them are factual assertions which are still to occur or to be proven. The DNA is considered to be intimately related to the species identity and hence no part of it should be controlled for commercial interest. In case of human beings, human DNA is unique and hence possesses intrinsic value of a sacred kind. It can also be put as 'Human DNA bears the image of God' and to tamper with them and own them for commercial and economic interests would hurt the sentiments of the many. The view that plants, animals and microorganisms comprising life on earth are part of the natural world into which we are born and hence the conversion of these species, their

molecules, or parts into corporate property through patent monopolies is counter to the interest of the people of the country and world, has been taken by many.

However most of the religious and ethical issues arise out of product patents which have been given to organs, cells, genes and proteins. Hence one possibility that could be accepted by such religious leaders could be the issuance of 'process patents', whereby only the process involved in the manipulation of particular genes are patented rather than the genes in itself.

Exciting invention in the field of bio technology have been made in recent years following the examples of the owners of bio tech patents companies with high investment in the field of bio technology now recognized the advantage of protecting and enforcing their intellectual property rights and in relatyion to this a series of ethical questions relating to the patent aspect has emerged. In the middle of this debate are ordinary citizens, often uncomfortable with the idea that something as fundamental as a gene can be patented but at the same time eager to see new medicines. The objection which is forwarded against genetic patenting is that genes are "products of nature" and therefore ought to be off-limited[157].

The next argument that is forwarded against D.N.A patenting is that such patents make important products more expensive and less accessible. The biotech industry claims that patents are necessary so that innovative, life-saving technologies can be developed. In actuality, patents enable companies to create a monopoly on a product, permitting artificially high pricing.

Patents on living organisms are morally objectionable to many people. Patenting organisms and their DNA promotes the concept that life is a commodity and the view that living being are "gene machines" to be exploited for profit. If it is possible to consider a modified animal an invention, are patents and human reproductive cells and their marketing far behind? Patents derive from concepts of individual innovation and ownership, which may be foreign to cultures which emphasize the sharing of

[157] The courts have recognized a "products of nature" doctrine and used it to reject some patent applications. However a counter-principle has also evolved[157] : Advocates of gene patents cite the sophistication of this work (i.e. gene patenting) in arguing that ownership rights are not being granted to scientists simply because they stumble on an aspect of nature, but rather because they are deploying complex techniques to manipulate nature in the service of human goals.

community resources and the free exchange of seeds and knowledge. Many disputes involving patent infringement cases emerged because of question related to obviousness, enablement or the priority of invention that had to be decided by the courts. More difficult were the questions about the ownership rights and privileges. For example, in the patent 'Unique T-lymphocyte line and products derived therefrom', the inventors used the spleen of a patient Mr. John Moore who suffered from hairy cell leukemia and came for treatment to Dr. David Golde at UCLA. As part of the treatment, his spleen was removed and Dr. Golde developed a cell line with enriched T-lymphocytes that produced large amounts of lymphocytes useful for cancer or AIDS treatment. Without Mr. Moore's initial knowledge or consent, but requiring his repeated visits to the hospital, Dr. Golde and the University of California applied for a patent on the cell line derived from Mr. Moore's spleen which was granted in 1984. Mr. Moore subsequently sued Dr. Golde and the University supreme Court. Both the Appeals Court and the Supreme Court recognized the novelty of Mr. Moore's claim Mr. Moore on the issue of conversion (unauthorized use of his body part), but recognized his right to be informed of what the physician was doing involving his health and well being. It's as irony that a person is not given any benefit of the substance which he himself had produced, and at the same time others are minting money from the same substance.

First World patenting of Third World genetic resources represents theft of community of biological resources.

Patents held by the industrialized world on biological resources from the developing world will serve as a tool for the North to accumulate more wealth from the already impoverished south. Microorganisms, plants, animals and even the genes of indigenous people have been patented for the production of pharmaceuticals and other products. Requiring developing nations to pay royalties to the wealthy industrial nations for products derived from their own natural resources and innovation in robbery. Moreover the developing world has never received compensation or recognition for these intellectual and technological contributions. Patenting life forms will exacerbate this inequality. This "bio-colonialism" will continue the pattern of a few transnational corporations profiting at the expense of genetic resources of the third world countries.

But biocolonist have their own defense; they argue that "Decoding the human genome will increase our knowledge a thousand fold times a thousand fold of the nature of Homo sapiens. And with that knowledge will come immense power. Before we create, we will almost certainly destroy, committing a new form of human selection, genomecide. Through systematic but simple foetel genetic tests in the next decade, we will ruthlessly search out and eradicate those human genes we regard as inferior,Certainly there will be great benefits a cure for AIDS malaria, maybe eventually nearly all of the disease that affect humanity. Genomics is the future of a whole new set of pharmaceutical industries that will create thousands of individually tailored drugs.

But the question is where to draw the line? Will one abort multi-celled fetuses because the tests show genes that code for Alzheimer's in later life? Would we now eradicate the former US President Ronald Reagan, whose Alzheimer's is genetically inherited, just after conception? What is the definition of an acceptable genetic human being? What is a valid human life?

Law and morality are inter-connected and some areas of law require the legal adjudicators to draw on morality in considering the decision making process. The patent law especially concerning the patenting of biotechnological inventions does just this. The best example of this would be Article 53 (a) of the European Patent Convention 1973, which does not allow the grant of patents "for inventions the publication or exploitation of which would be considered to be contrary to 'ordre public or morality". Most of the national patent laws of various countries embrace the moral standards within its ambit. When the legislatures enact patent laws, the moral standards of the community to which they belong to are one of the factors which affect their content. Moreover, the patenting system cannot be considered to be an ethically neutral concept. A system can be considered to be ethically neutral when it does not affect A's interests vis-à-vis B's interest. The whole crux of patents is to exclude others from access to information contained in the claims and hence it cannot be considered to be morally or ethically neutral. This act of excluding others to protect your interest will inevitably affect some one else's rights in some way or the other.

Patenting within the biotechnological sphere and the subsequent opposition proceedings which have been undertaken by NGO's such as the Greenpeace, which have become worried by prospects such as the patenting of life, have led courts to highlight the relationship between patents and morality. However it has to be kept in mind that the concept of morality is relative to the values prevailing in society. The decisions based on morality should not be based on what some members of the public find objectionable, but should include a detailed analysis of the effect on human health, economic impact, environmental issues and opinion of the population as a whole. The main point, however is that non-patentability would only mean that the invention is not the subject of any property rights, it can still be used and worked even if it is contrary to public interest and morality as it still lies in the public domain[158].

18.7 Why say NO to Life patenting[159]?

The WTO has forced countries to introduce laws that allow the patenting of life forms and living organisms. In India, this was done through the Patents Act of 1970. Due to the introduction of such a monopolistic set up where biotechnological inventions can be patented, it has led to an epidemic of Biopiracy and the patenting of traditional knowledge.

The following are the other reasons which have been laid down to object life form patenting.

i. Farmers would be obliged to pay royalties on every generation of plants and livestock they buy and reproduce for production purposes.
ii. Breeders will no longer have free access to germ plasm for developing new varieties of plants and animals.
iii. Consumers will end up paying high prices for food, medicine and other biotechnological products.
iv. In the end, public research which is paid for by all will be privatized by a few.
v. Food supply will be threatened by monopolistic control over genetic resources.

[158] http://www.legalserviceindia.com/article/l254-Patenting-Recent-Biotechnological-Inventions.html
[159] ibid

vi. The concept of Human rights will be threatened as human beings, and parts of their bodies will become the exclusive property of the patent holders.

vii. Animal welfare will become a thing of the past as the patent system stimulates genetic engineering of animals for production of food and medicine no matter how they suffer.

viii. The main objection to the patenting of life forms are that DNA is a product of nature and not a product of human ingenuity.

18.8 Whether Patent Law Protects Biotechnological Inventions

The relationship of law and morality is particularly foundt in the sphere of patent law.

When Louis Pasteur in 1873 received US Patent 141,072, claiming 'yeast, free from organic germs of disease, as an article of manufacture', first patent concerning a micro-organism was granted.

In essence, the India Patents Act gives only very limited protection to research-based pharmaceutical companies. Patenting of human material in the form of gene sequences is considered to be wrong as it amounts to commercialization of life. Failure of the basic patent principles to cater to the needs of genetic inventions has given rise to ambiguities for companies concerned with bio-technology.

18.9 Factors determining the question of patentability

Protection of intellectual property is at the core of the business for biotechnology firms. When considering these issues, one also needs to recognize that legal regimes other than patent systems are typically relied upon to address other public interests, such as the environmental or medical safety of products, efficacy of products, and unfair competition that may occur in the assertion of patent rights. The transparency of the patent system supports ethical scrutiny of biotechnology and can help inform the bioethics debate.

Oliver Mills has suggested that in order to protect adequately biological invention, effectively harmonizing legislation regarding patentability criteria is necessary.

18.10 Dangers involved

Han Somsen has differentiated between pre-grant and post-grant concerns. He is of the view that pre-grant objections relate to subject-matter, requirements and disclosure whereas post-grant objections revolve around blocking effects of patents on research as well as health-care. Prof Gardner has put: "Our experience with animals suggests that there would be a very real danger of creating seriously handicapped individuals if anybody tries to implant cloned human embryos into the womb."

Biological inventions possess properties that pose unique challenges to the patent system. We always hear that morals or ethics are impeding bio-tech progress, but in reality these ethics have ensured a check whether small over biotechnological inventions. Patenting human genes amounts to a form of modern slavery since it involves the dismemberment of women and their piecemeal sale to commercial enterprises.

18.11 Benefits

Decoding human genome will be of great benefit to human race, a cure for AIDS or maybe eventually all of the diseases that afflict humanity can be wiped off. So we can say Genomic is the future of a whole new set of pharmaceutical industries that will create thousands of individually tailored drugs and consequently billions of dollars would be needed to invest in these complex researches. Where will this money come from? Obviously from the people, who will in turn benefit from this research. And regarding the high pricing of life saving technologies, it is it has observed that many of the pharmaceutical companies sell these drugs at a much lower rate than feared.

Defenders of such patents such as biotechnology firms, joined by some researchers in academia and the pharmaceutical industry argue fiercely that without patents society won't benefit from revelations about the molecular roots disease. Moreover the arguments that patenting DNA promotes the view that life is a commodity, cannot be accepted because it is not that the main aim of the DNA patenting to earn profit or to use it for someone personal interest, on the contrary the overall aim of the patent system is to promote the public interest and to provide a fair reward to inventors. The

patents system is said to be justified because it provides an important incentive for the development or new products and technologies related to healthcare.

18.12 Conclusion

1. A ban on patenting genome sequences would be both impractical and unrealistic and tighter rules are needed on the conditions under which such patents are granted.
2. The most commonly heard refrains from those critical of the private sector's control over biotechnology is that no patents should be granted on DNA sequences because such stretches of DNA are 'natural', and therefore cannot qualify as inventions (which is what the patent system was set up to protect).If the human genome - and all its contents - belongs to anyone, it should be commonly owned by all mankind. Staking claims to the sequences that make up individual genes, even if previously unknown is portrayed as the ultimate form of "biopiracy".
3. Unfortunately, perhaps, such a viewpoint appears somewhat utopian. We live in a world where society, through its patent laws, has already agreed that certain kinds of products can be patented. A likely candidate, for example, would be a gene sequence that forms an essential element of a novel diagnostic test for a disease.
4. But that does not mean that nothing can - or should - be done about DNA patents.
5. In future, a patent should only be granted on a gene if the social benefit likely to emerge from knowing the genetic code for that gene can be clearly defined. Patents on gene sequences should no longer cover all possible uses of that sequence, some of which may be unknown. In this regard it is submitted that patents must satisfy the condition of not being contrary to morality or 'ordre public' and suggest that patent offices should seek general ethical guidance, as necessary, from relevant bodies.

DNA patents should be the exception rather than the rule"."
It is not as simple as, 'Patents, good or bad?' or 'Licensing, good or bad? "The mission should be to make sure that all this research benefits people".

William Heseltine (President, Human Genome Science) has interestingly noted that trying to patent a human gene is like trying to patent a tree. You can patent a table that you build from a tree, but you cannot patent the tree itself.

By signing "Budapest Treaty on the International Recognition of the Deposit of Micro organisms for the Purposes of Patent Procedure", India can assist in the standardization process of biotechnology pate in the country. Since patent system cannot survive in a moral vacuum, so we must not let any conflict continue between bio-technology and patents regarding it.

19 Biotechnology-

19.1 Concept definition:

A combination of biology and technology. It is used to describe developments in the application of biological organisms for commercial and scientific purposes. So "bio" stands for biology and the science of life, and "tech" stands for technology, or the tools and techniques that the biotechnologists have in their workbox. Those tools and techniques include microorganisms and a range of methods for manipulating them, such as genetic engineering[160].

20. Genetic engineering

20.1 Concept definition:

1) The complex of techniques for the production of new genes and the alteration of the structure of the chromosomes to produce effects beneficial to man, in agriculture and medicine

2) The intentional production of new genes and alteration of genomes by the substitution or addition of new genetic material.

[160] It is a vast subject to be discussed on, but required to mention in research as DNA is part and parcel of the same and we cannot ignore this topic.:the scope has been narrowed down in websites Available at http://www.ndsu.edu/ndsu/academic/factsheets/ag/biotech.shtml and http://www.eco-business.com/business/algaetechinternational/and http://www.lycos.com/info/biotechnology--technology.html and http://education-portal.com/articles/Associate_of_Biotechnology_Degree_Overview.html(last Accessed on 25th October 2007)

20.2 Fundamentals of Genetic Engineering

Genetic engineering is the process of transferring specific genes from the chromosome of one organism and transplanting them into the chromosome of another organism in such a way that they become a reproductive part of the new organism. The process that produces the resulting recombinant DNA involves four steps:

i. The desired DNA is cleaved from the donating chromosome by the action of *restriction enzymes*, which recognize and cut specific nucleotide segments, leaving a "sticky end" on both ends. The restriction enzymes also splice the receiving chromosome in a complementary location, again leaving "sticky ends" to receive the desired DNA.

ii. The desired DNA fragment is inserted into a vector, usually a plasmid, for transfer to the receiving chromosome. Plasmids are an ideal vector because they replicate easily inside host bacteria and readily accept and transfer new genes. Plasmids are circular DNA molecules found in the cytoplasm of bacteria that bond with the desired DNA fragment with the help of the joining enzyme, *DNA ligase*, to create the resulting *recombinant DNA*.

iii. When the host cell reproduces, the plasmids inside also reproduce, making multiple clones of their DNA. Because the plasmid DNA contains the desired as well as unwanted DNA clones, the entire product is referred to as a *gene library*. The desired gene is similar to one book in that library.

iv. To recover the desired DNA, the current technology is to screen unwanted cells from the mixture and then use gel electrophoresis to separate the remaining genes by movement on an electric grid. Gel electrophoresis uses a positively charged grid to attract the negatively charged DNA fragments, thereby separating them by size, because the smaller ones will migrate the most. Radioactive or fluorescent probes are added, which attract and bind with the desired DNA to produce visible bands. Once isolated, the DNA is available for commercial use.

In 1973, researchers Cohen and Boyer created an interesting model for screening the host cells to finds the desired DNA fragment. In their experiment, they inserted the desired DNA and a DNA segment that made the host bacteria resistant to a particular antibiotic, tetracycline. When the antibiotic was applied to the general population,

only those bacteria that had received the plasmid survived—so they knew their desired DNA fragment was located in the surviving bacteria.

20.3 Current Recombinant Cloning Technology

Reverse transcriptase is an enzyme that acts opposite of normal transcriptase. It uses RNA to code for DNA. It is also found in the virus linked to AIDS.

A more advanced method of producing DNA clones uses the enzyme reverse transcriptase and mRNA in a four-step process, which creates a pure segment of desired genes:

1. mRNA is made by a selected cell particularly for its genetic characteristics.
2. mRNA splices out the interons.
3. mRNA is isolated and used as a template with reverse transcriptase to make the complementary DNA.
4. The DNA product therefore contains only the desired DNA segment and the host cell will continue to produce the product.

With this type of emerging technology, the "shotgun" approach to cloning is simplified by not copying the entire genome of the individual, but only the specific genes required

20.4 Human Disorders and Gene Therapy

Genetic disorders are the harmful effects on an individual caused by inherited genetic diseases or mutations. Usually genetic disorders are recessive, so they are only expressed in a small percentage of the population, but a much larger percentage are carriers. When expressed in the homozygous recessive individual, they often code for the wrong protein or amino acid sequence. There are many genetic disorders; however, two are common in today's population: hemophilia A and sickle-cell anemia.

Hemophilia A is a recessive sex-linked genetic disorder that is exhibited by approximately 1 in every 10,000 Caucasian males. Multiple genes code for the multistep process of blood clotting. Mutation in any one of them creates hemophilia

A, the inability to form blood clots. Individuals with this disease must avoid all cuts and bruises, both internal and external. In severe cases, the individual may lose massive amounts of blood.

Sickle-cell anemia is a recessive genetic disorder that affects 1 in every 500 African Americans. A mutation of an allele causes the allele to code for a sickle-shaped hemoglobin molecule. The defective hemoglobin molecules do not transport as much oxygen as the hemoglobin in normal red blood cells because they tend to rupture. They also sometimes wedge in a blood vessel, blocking the flow of blood cells. Tissues and organs downstream from the obstruction may suffer serious damage. Interestingly, sickle cells are a survival advantage in certain areas because they are a defense against malaria and may protect some people from the disease.

Although most genetic disorders cannot be treated because of technology limitations, certain ones such as phenylketonuria (PKU) can be treated if discovered in time. For instance, a baby with PKU is maintained on a low-phenylalanine diet to prevent mental retardation caused by its buildup.

Most humans inherit genetic disorders because of the improper functioning of a particular gene sequence. In theory, replacing the defective gene with a healthy one should solve the problem, which is the essence of gene therapy. Although in its infancy as a treatment for disorders such as hemophilia and sickle-cell anemia, patients have received genetically engineered cells as an experimental treatment for missing genes. At this time the data are incomplete regarding the results. Currently, researchers are attempting to engineer cells, usually from bone marrow, to enhance the abilities of immune cells to fight off cancer and resist infection by HIV. This approach may lead to an effective treatment for nonhereditary diseases.

21. Human Genome Project

The Human Genome Project (HGP) is the most exciting breakthrough in human genetics in modern times! Geneticists from around the world collaborated to determine the nucleotide sequence for the complete human genome. This genetic map gives the location of each of the approximately 100,000 human genes composed of roughly 3 billion nucleotides.

The immense value of this knowledge will provide new understanding of how all genes work, how they are regulated, and how and why they create biological molecules. The human genome can then be compared to other known animal genomes to examine similarities and differences that may be useful in the creation of new genetic recombinations. Some of the knowledge gained may allow gene replacement and other gene-therapy strategies. For instance, it is known that sharks never contract cancer. If there is a cancer-inhibiting gene in sharks that could be incorporated into humans with no side effects, another serious health concern could be avoided. The possibilities open genetic engineering as a profitable, socially beneficial enterprise in the near future. It is estimated that there are more than 3,000 human genetic disorders!

21.1 Legal and Ethical Considerations

Many challenges to the new technology need to be addressed so that the research and treatment may proceed without violation of public trust and confidence. Legal and ethical challenges can be classified into the following question categories:

- Who has the right to the cure?
- What will be the cost and availability?
- Do we have the right to alter a person's genes?
- Do we have the right to control the genetic complement of the human population and other eugenic considerations?
- Several scientific questions also pose additional considerations:
- The development of new genes combinations increases genetic diversity, which is normally considered a positive effect, but may have unintended, unforeseen consequences.
- Creating new genes may also create new pathogenic organisms for which we have no cure.
- Do we have the ability to safely handle new genetically altered organisms?
- Certain bacteria have already been utilized to clean up oil spills; are there other uses?

The use of *recombinant DNA* technology has become commonplace as new products from genetically altered plants, animals, and microbes have become available for

human use. In 1997, Dolly made headlines as the first successfully *cloned* large mammal (sheep). Since then there have been many similar advances in medicine, such as treatments for cancer; many advances in agriculture, such as transgenic insect-resistant crops; and many advances in animal husbandry, such as growth hormones and *transgenic* animals (an animal that has received recombinant DNA).

Most biotechnologists envision DNA technological applications as one of the new frontiers in science with tremendous growth and discovery potential.