CHAPTER 11

CONCLUSION

GENETIC PATENT MODEL FOR INDIA

The size off public and patent domain in a country depends on different factors incorporated within its patent law. Chapters 4 to 9 elucidate the variation in sizes of public and patent domain of gene based inventions in US, Europe and India due to differences in the constitution of patentability and morality requirements. Furthermore, Chapter 10 elucidates the differences in scope of research exemptions and its impact on sizes of public domain with regard to genetic inventions in each country/region. The differences in constitution of requirements and research exemptions can be attributed to the divergence in development level and social, economic and ideological conditions in those countries/regions. As the ideal configuration of each requirement that would promote utmost progress in genetics varies from country to country based on various conditions, it is not possible to define a utopian balance between all requirements that would work for all countries and the ideal configuration of each requirement to promote optimal progress of science differs from country to country. With this limitation in mind, this chapter points out the problems with existing configuration of requirements in India and proposes a solution in the form of a model that balances the size of patentability requirements with the size of research exemptions for promoting rapid progress of genetic science. The model proposed in this chapter is one way of solving problems arising out of diversity and can be used in combination with other solutions.

Patent/public domain Variance

Each of the requirements has differential treatment in different countries/regions with regard to genetic inventions. The scope of subject matter requirement is broad in USA, narrow in India and moderate in Europe. While all gene based inventions except human beings would pass through the subject matter filter in USA, genetically modified multicellular organisms, human beings and gene therapies are not patentable in India and genetically modified nonmamalian multicellular organisms, human beings and gene therapies are not patentable in Europe. The subject matter filter, which is the

gatekeeper filter, allows most gene based inventions to be eligible for patent domain in USA, less gene based inventions in Europe and very less gene based inventions in India. So, the size of patent domain created by subject matter filter with regard to gene based inventions is larger in USA than Europe and that of Europe is larger than in India.

By imposing a straight forward ban, the Indian patent law keeps lot of gene based inventions outside the scope of the incentives for progress offered by the patent system, which means that such inventions cannot be eligible for a patent even if they are useful and novel as they don't pass through the subject matter filter. On the other hand, the US Patent Law provides patent incentives to most gene-based inventions through its broad subject matter filter. Prima facie, the US subject matter policy seems better when compared to the Indian policy because it encourages research on all gene based inventions by keeping the gates open for all of them and granting patents only if they are worthy through satisfaction of all other requirements rather than blocking them at the entry stage and not subjecting them to the other requirements.

The Utility Filter has a different dynamic in relation to genetic inventions when compared to the subject matter filter. The US Patent Law requires specific, substantial and credible utility, which is tough to satisfy when compared to the made and used in an industry requirement in Europe and India. Gene based inventions can pass through the utility filter easily in Europe and India than in USA. For example, if the Fisher case dealing with an invention relating to ESTs of maize plant citing uses such as molecular marker, promoter, use in PCR and so on, which was decided by a US court to lack utility is decided in India or Europe, the courts would hold that the invention possesses utility. The fact that the EST can be reproduced and used in an industry for a purpose such as promoter or marker or probe would be sufficient for utility requirement in India and Europe. So, the size of patent domain created by the utility filter with regard to genetic inventions is larger in Europe and India than in USA.

Heightened utility requirements in USA may be attributed to the broad subject matter requirement, which allows most gene based inventions to get to the utility filter making it necessary to coin a stringent test to permit only inventions that are useful to the society to pass through it. On the other hand, the European and Indian requirement, which comes after a narrow subject matter filter does not have too many inventions running into it and is an easy passage for most gene based inventions.

The novelty requirement for genetic inventions is generally uniform in all three countries at a broad level. All of them assess novelty of gene related inventions based on similar criteria using common basic principles. Among USA, Europe and India, USA has a slightly broader novelty requirement through more grace periods and slightly narrower one by following the first to invent system, which gives priorty to early conception. US patent law forces inventors to maintain laboratory note books for proof of conception in case of interference. An inventor can lose ownership of a genetic invention if he does not maintain lab note books. This increases burden over inventors but does not impact scope heavily. Therefore, the novelty filter is largely uniform with US requirement being slightly broad.

Non-obviousness requirement is very broad in India and USA when compared to Europe. It is broader in India when compared to USA. It is easy for a gene based invention to pass through the non-obviousness requirement in USA than in Europe and it is much easier in India. For example, isolation of a DNA sequence coding for a protein in humans from a monkey gene library would be non-obvious in USA but might most probably be obvious in Europe due to homology between species. In India the gene sequence would be non-obvious because it would have economic implications. So, the non-obviousness filter creates a wider patent domain with regard to genetic inventions in India than in USA and in USA than in Europe. This filter, which is by far the most important filter for determining patent grants to worthy inventions, has not been properly defined

in India. By coining a very narrow subject matter filter and very broad non-obviousness filter, the Indian patent law allows limited gene based inventions to pass through the subject matter requirement and makes it very easy for them to pass through the non-obviousness requirement, thus leaving scope for unworthy inventions to get a patent grant.

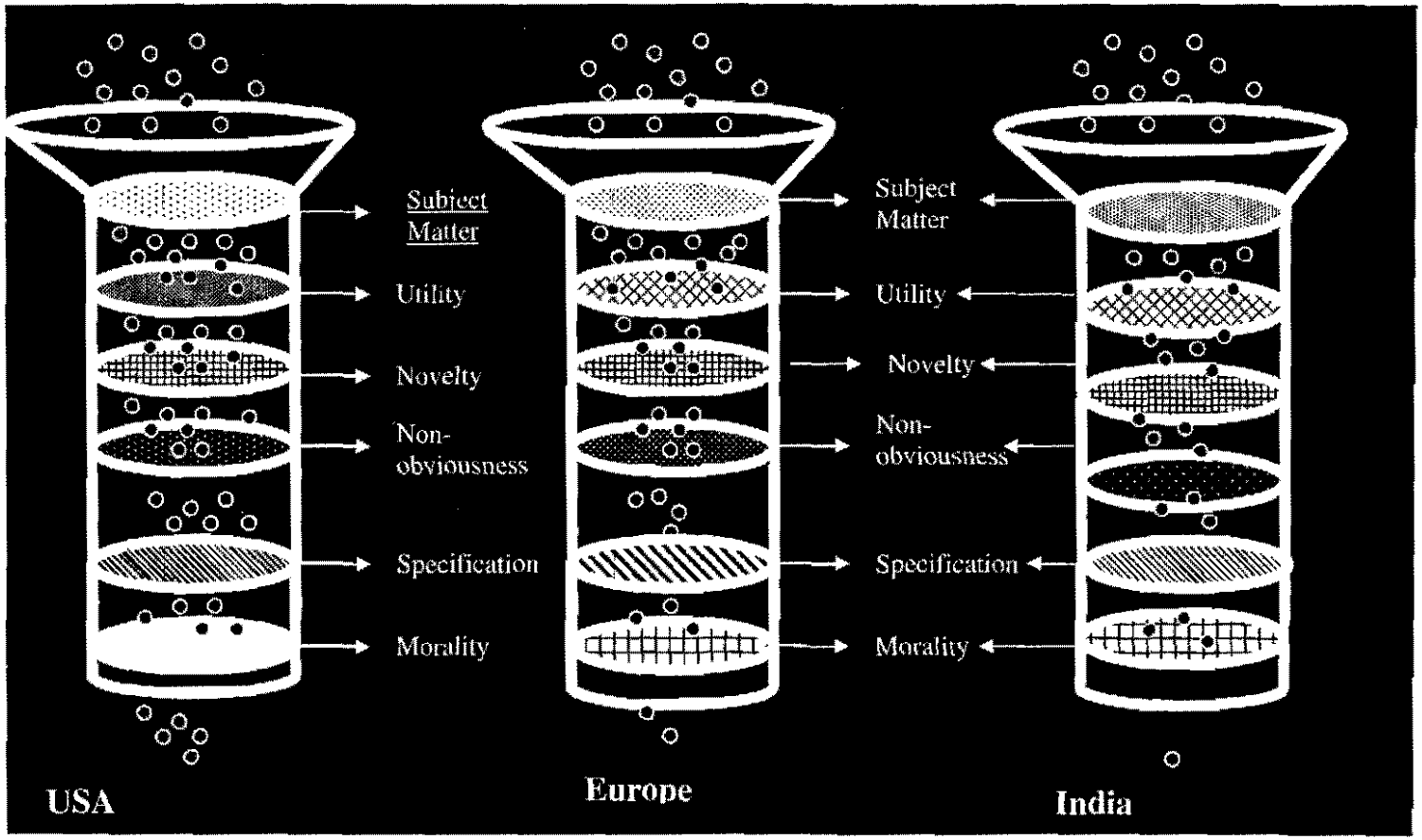
The written description and enablement filter with regard to genetic inventions is narrow in USA, broad in Europe and not clearly defined in India. This filter creates a large patent domain in Europe and narrow patent domain in USA. The US patent law requires separate written description and enablement requirements as opposed to a common disclosure requirement in Europe. For example, gene sequence and a method cloning may be enabled in Europe by describing the sequence based on only function, without describing the structure. However, it cannot be enabled in USA without describing the structure. The Indian enablement filter is not clearly interpreted in relation to gene based inventions and is shown as medium in the figure below. So, the written description and enablement requirement in Europe creates a large patent domain and small public domain when compared to that of USA.

Morality and public order forms an integral element of patentability analysis relating to genetic inventions in Europe and India and does not play a role in USA. So, to be eligible for a patent in Europe and India, a gene-based invention has to be moral. For example, in a patent application filed by WARF in USA and Europe over primate embryonic stem cells, a patent was granted in USA but it was rejected in Europe based on morality. The same was the case with a patent relating to a transgenic mouse for research on baldness. The patents would be rejected in India also on moral grounds along with other grounds. The morality filter is not existant in USA and creates a large public domain with regard to genetic inventions in Europe and India.

The configuration of patentability requirements in USA, Europe and India are represented in the figure below.

Figure 10.1

Diagram 1 - USA Diagram 2- EU Diagram 3 - INDIA



The figure shown above has three diagrams showing the configuration of patentability filters relating to gene-based inventions in USA, Europe and India. Diagram 1 shows the arrangement of patentability filters in USA. Taking USA as a bench mark for purposes of analysis, the European subject matter is narrow, utility is broad, novelty is slightly narrow and non-obviousness is narrow in comparison to patentability filters in USA. Unlike the US Patent Law, the European patent law provides for morality analysis in patentability determination. The Indian diagram shows that the subject matter filter is very narrow, utility slightly broad, novelty almost same and non-obviousness broad when compared with USA. Like Europe, Indian patent law provides for a morality analysis in its patentability determination.

USA requirements are overall very broad when compared to requirements in Europe and India. Through its broad subject matter filter encompassing most gene-based inventions; USA encourages research in multifarious fields relating to genes. It then tests the utility of each invention thoroughly through its specific, substantial and credible usefulness requirement. By having relaxed novelty and non-obviousness filters, the US Patent Law allows gene-based inventions to get patents easily. On the whole, the US patent regime is more conducive to a wide range of gene-based inventions and therefore creates opportunities for more inventions to enter into the patent domain than in Europe and India.

In Europe, the size of subject matter is narrow than in USA and certain gene-based inventions are not allowed to pass through it, thus reducing the list of inventions that can get to the next filters. Though European patent law has a broader utility filter, the novelty and non-obviousness requirements are much stringent than In USA making it difficult for whatever gene based inventions pass through the subject matter requirement, to be eligible for a patent.

Furthermore, inclusion of morality analysis in patentability determination makes it much tougher for gene-based inventions to pass through patent eligibility. Compared to USA, the size of patent domain in Europe is much smaller than the one that is possible under the US Law.

The Indian patentable subject matter requirement is very narrow when compared to USA, which means that a very limited number of gene based inventions can pass through this filter. The limited number of inventions that pass through the subject matter filter have a slightly stringent utility requirement, similar novelty filter and very easy non-obviousness filter to encounter when compared with USA. A gene-based invention also has to pass through the morality analysis before being eligible for a patent. The cumulative effect of all filters result in a narrow patent domain when compared to Europe and USA. The existence of a broad non-obviousness filter makes it easy for eligible subjects to get a patent but that does not overcome the very narrow subject matter requirement.

As a result of the cumulative effect of all filters, the size of patent domain is very large in USA, moderate in Europe and SMALL IN India, which means that the size of public domain is narrow in USA, moderate in Europe and large in India. The scope of exemptions for research, which creates a defacto public domain, is narrow in USA, broad in Europe and India at different levels. The appropriate constitution of each patentability filter and research exemptions to promote optimal progress of gene-based inventions is still debatable and the ideal balance of all filters depends on circumstances in each country. The figure shown above has three diagrams showing the configuration of patentability filters relating to gene-based inventions in USA, Europe and India. Diagram 1 shows the arrangement of patentability filters in USA with regard to genetic inventions. Taking USA as a bench mark for purposes of analysis, the European subject matter is narrow, utility is broad, novelty is slightly narrow, non-obviousness is narrow and specification is broad. Unlike the US Patent Law,

the European patent law provides for morality analysis in patentability determination. The Indian diagram shows that the subject matter filter is very narrow, utility slightly broad, novelty almost same and non-obviousness broad with regard to genetic inventions when compared with USA. Like Europe, Indian patent law provides for a morality analysis in its patentability determination.

USA requirements are overall very broad when compared to requirements in Europe and India. Through its broad subject matter filter encompassing most gene-based inventions; USA encourages research in multifarious fields relating to genes. It then tests the utility of each invention thoroughly through its specific, substantial and credible usefulness requirement and stringent written description and enablement requirement for gene based inventions. By having relaxed novelty and non-obviousness filters, the US Patent Law allows gene-based inventions to get patents easily. On the whole, the US patent regime is more conducive to a wide range of gene-based inventions and therefore creates opportunities for more inventions to enter into the patent domain than in Europe and India.

In Europe, the size of subject matter is narrow than in USA and certain gene-based inventions are not allowed to pass through it, thus reducing the list of inventions that can get to the next filters. Though European patent law has broader utility and enablement filters, the novelty and non-obviousness requirements are much stringent than in USA making it difficult for whatever gene based inventions pass through the subject matter requirement, to be eligible for a patent. Furthermore, inclusion of morality analysis in patentability determination makes it much tougher for gene-based inventions to pass through patent eligibility. Comparatively, the size of patent domain in Europe is much smaller than the one that is possible under the US Law.

The Indian patentable subject matter requirement is very narrow when compared to USA, which means that a very limited number of gene based

inventions can pass through this filter. The limited number of inventions that pass through the subject matter filter have a slightly stringent utility requirement, similar novelty filter and very easy non-obviousness filter to encounter when compared with USA. The enablement requirement is vaguely defined in India. A gene-based invention also has to pass through the morality analysis before being eligible for a patent. The cumulative effect of all filters result in a narrow patent domain when compared to Europe and USA. The existence of a broad non-obviousness filter makes it easy for eligible genetic subjects to get a patent but that does not overcome the very narrow subject matter requirement.

As a result of the cumulative effect of all filters, the size of patent domain for genetic inventions is very large in USA, moderate in Europe and SMALL IN India, which means that the size of public domain is narrow in USA, moderate in Europe and large in India. The broad size of patent domain created by US patent law when compared to Europe and India is elucidated in the patent grants data provided in the tables shown in Annexure 2. The Annexure shows a list of genetic patents granted to Indian assignees in USA. About 32 gene based patents have been granted in USA to Indian assignees out of which only 11 have been filed in Europe also and 6 in India also. Out of the 11 genetic patents filed in USA and Europe, only four have been granted and others have been rejected. The fact that 7 gene based patents that have been granted in USA were filed in Europe but were not granted is an indication that the European patent system is not as conducive to gene based inventions as USA. Among the 31 patent grants to Indian companies over gene based inventions, the fact that only 11 have been filed in Europe is an indication that Indian companies have more business interests in USA than in Europe, which might be because of unfriendly patent regime to genetic inventions in Europe. It should be noted that out of the 31 genetic patents granted in USA to Indian assignees only 6 have been filed in India, which once again indicates that the Indian patent system is not friendly to gene based inventions.

The table below shows the list of genetic patents granted to Indian companies in USA, Europe and India.

Table 11.1- Genetic Patent Grants

Country → / Company/Institutes ↓	USA	Europe	India
Council of Scientific and Industrial Research	22	2	0
Dabur Research Foundation	2	2	1
National Institute of Immunology	2	0	1
Ranbaxy Laboratories Limited	3	1	0
Reliance Life Sciences Pvt. Ltd.	1	0	0
Wockhardt Limited	1	1	1

The table shows a list of six companies having 31 genetic patents in USA. Out of the six companies only four companies have patents in Europe (totally only 6 patents) and only three companies have genetic patents in India (totally 3). The fact that Indian companies possess more genetic patents in USA, less in Europe and very less in India indicates that the US patent system is very friendly to genetic inventions when compared to Europe and India. For example, CSIR has 22 genetic patents in USA, 2 in Europe and 0 in India. The patent distribution leans largely towards USA. Most of the patents filed in USA were not filed in India or Europe as they would not be eligible to get a patent in India or Europe due to stringent patentability requirements that tilt the balance in favour of public domain.

To elucidate the point further, the table shown below shows a list of selected genetic patents granted in USA, which were filed in Europe but rejected due to stringent patentability requirements.

Table 11.2- Genetic Patent Grants and Rejections

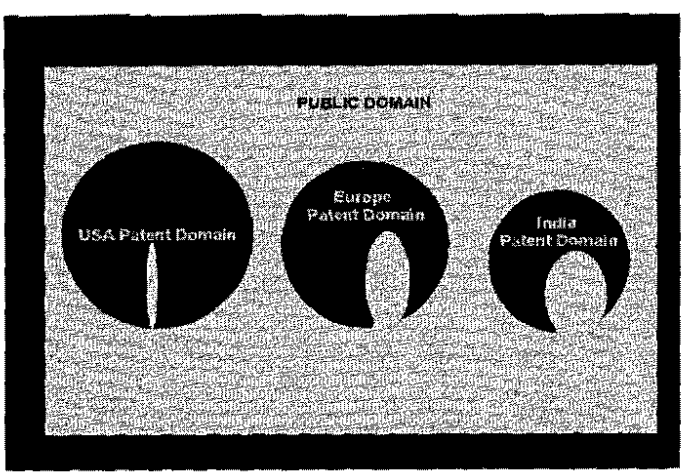
Title	USA	Europe
Embryonic Stem Cells		
Hepatocyte lineage cells derived from pluripotent stem cells	Patent Granted-US6458589	Filed but rejected
Methods for providing differentiated stem cells	Patent Granted-US6576464	Filed but rejected
Hematopoietic differentiation of human pluripotent embryonic stem cells	Patent Granted-US6280718	Filed but rejected
Primate embryonic stem cells	Patent Granted-US6200806	Filed but rejected
Gene Therapy		
Molecular constructs with a carcinoembryonic antigen (CEA) transcriptional regulatory sequence.	Patent Granted-US6699690	Filed but rejected
Molecular constructs containing a carcinoembryonic antigen regulatory sequence	Patent Granted-US6337209	Filed but rejected
Molecular constructs comprising a carcinoembryonic antigen (CEA) transcriptional regulatory region	Patent Granted-US6300490	Filed but rejected
Isolated nucleic acid molecule encoding alternatively spliced prostate-specific membrane antigen and uses thereof	Patent Granted-US5935818	Filed but rejected
Genetically Modified Organism		
Ribozyme treatment of diseases or conditions related to levels of NF-.kappa.B	Patent Granted-US6410224	Filed but rejected
C-myb ribozymes having 2'-5'-linked adenylate residues	Patent Granted-US5817796	Filed but rejected
Rel a targeted ribozymes	Patent Granted-US5658780	Filed but rejected
C-myb targeted ribozymes	Patent Granted-US5646042	Filed but rejected
Gene Sequences		
Oligonucleotide primers having SEQ ID NOs. 1 to 21 and a process for detection of parasite Salmonella using oligonucleotide primers	Patent Granted-US7041482	Filed but rejected
Primers for screening schizophrenia and a method thereof	Patent Granted-US6764824	Filed but rejected

Table 11.2 shows patents relating to human embryonic stem cells gene therapies and genetically modified organisms, which were filed in both USA and Europe but rejected in Europe because of not satisfying patentability requirements. The patents would not be granted in India also as the Indian patentability requirements are more stringent than the other two countries. The table clearly elucidates that the patent regime in Europe and India is not conducive to granting patents over genetic inventions. Among Europe and India, India is less friendly than Europe.

As seen from the above the size of genetic invention based patent domain is very small in India and small in Europe when compared to USA. On the other hand the scope of exemptions for research, which create a defacto public domain, is narrow in USA, broad in Europe and very broad in India at different levels. As a result the large patent domain created in USA is not accessible to public due to a very narrow research exemptions. The narrow patent domain of genetic inventions is reasonably accessible in Europe and the very narrow patent domain of gene based inventions is easily accessible for public use in India. The accessibility of genetic patents to general public is illustrated in the figure below.

Figure 11.2

Research exemptions and defacto public domain



The figure shows that the large patent domain in USA is well safeguarded with limited research exemptions. There is a reasonably large hole in the European patent domain, which gives the right to public to make use of gene based inventions for research and private purposes. The narrow patent domain in India has a large hole in the form of defacto public domain and the public can freely access genetic patents and use them for research or experiments without much liability.

Consequences of existing filters

The differences in configuration of patentability filters for genetic inventions gives rise to benefits and disadvantages to each country at micro and macro levels.

USA

Among the three regions, USA has the broadest patent domain and most narrow public domain for gene-based inventions. The US Patentability filters are broadly and flexibly configured for gene-based inventions. The broad configuration not only allows a wide range of inventions to be eligible for patent but also makes it easy for them to satisfy all requirements. While the patentability filters are very broad, the scope of exemptions for research is very narrow. As a result, it is easy for a gene related invention to get into the patent domain in USA and also easy to prevent others from using the patented invention for research without authorization due to the narrow public domain. In other words, an inventor can get a patent very easily because of flexible patentability requirements but a researcher cannot use a patented invention without liability due to narrow scope of research exemptions. Based on the manifestation of its principles, it can be said that the US Patent Law is in favor of gene related inventions and inventors. The consequence of such a situation

is encouragement of progress in the field of genetic engineering through patent incentives. It is believed that the dominance of biotech industry in USA is partly due to their broad and receptive patent domain. The US patent system not only attracts patents from within but also patents from other countries. As seen in the tables in chapter 2 and in this chapter, Indian companies have filed and acquired lot of genetic patents in USA than in Europe and India. However, the over broadening of the patentability filters as in Laboratory Corp. and other cases and narrowing down of research exemptions, in Duke and other cases, scholars believe, would block the progress of genetic research.

EUROPE

Europe has a narrow genetic patent domain and broad public domain when compared to USA. In Europe, the law relating to patentability requirements is narrow when compared to USA. Not many gene-based inventions are eligible for a patent grant and it is not very easy for eligible gene based inventions to get through all filters. As a result the range of inventions that receive the patent incentives offered by the patent system are much less than the ones compared to USA. Moreover, the scope of research exemptions is broader than that in USA and makes it easy for researchers to use the patented inventions without permission from the patent holder. The result is a patent domain, which is not very much in favor of an inventor in the field of genetics because it is not easy for him to satisfy all requirements and even on satisfaction of all requirements, it is not easy to prevent others from using an invention without permission due to broader public domain in comparison to USA. So, when compared to USA the encouragement offered to genetic engineering by patent regime is not very high.

INDIA

India has a very narrow genetic patent domain and a very broad public domain when compared to USA. The Indian patentability requirements are very narrow when compared to USA and their research exemptions are very broad. In India, it is very tough for a gene-based invention to pass through the patentability filters because of the very narrow range of inventions eligible for a patent. Though the utility, novelty and non-obviousness filters are slightly broad, the fact that the subject matter is very narrow makes the Indian patentability requirements very narrow. The fact that subject matter is narrow and non-obviousness is flexible means that limited inventions get into the patent eligibility process and those that get into the process pass through the requirements easily. The enablement requirement is very narrow and ambiguous. As a result, the Indian patent system grants patents over a small group of inventions without proper test to determine the inventive step, making it possible for unworthy genetic inventions to get into the patent domain. Furthermore, an invention that gets into the patent domain can easily be pulled into the public domain due to wide scope of research exemptions. A researcher can easily use the genetic invention, which has been granted a patent without permission. In other words, in India, it is tough for an inventor to get a patent over a gene based invention and also tough to prevent others from using his invention. As a result the incentives offered by the patent system for promotion of progress in gene technologies is very low.

Due to narrow patent domain and very large and flexible public domain, the patent system in India does not play an important role in promoting the progress of gene technology. So, the researchers in India are put at a distinctive disadvantage, as they cannot prevent others from using their research products through the patent regime. The result is that their incentives to develop new products are stunted due to high possibility of free riding.

However, the differences in the patent law in different countries offer distinctive advantages to an Indian inventor.

The US has a patent regime that favors a genetic inventor and India has a patent regime that favors the public more than the inventor or patent holder. An Indian inventor can use these differences for his advantage. Though an Indian inventor cannot get a patent in India on most gene related technologies, he can get a patent in USA very easily and make profits using the US patent domain. Opportunities of making profits in USA provide the Indian inventor incentives to invent new technologies, which in turn promote progress of technology in India. There won't be too many impediments for an inventor in terms of acquiring authorization from patent holders to carry out research because the scope of research exemptions is very broad and most inventions patentable in USA are not patentable in India. Due to the broad genetic public domain created by narrow patentability scope and broad research exemptions, an inventor in India can use technology patented in both USA and India without any liability in order to help his research cause at zero or nominal cost. In other words, the broad public domain allows an Indian inventor to use a patented invention without liability and the strong US patent regime allows him to get a patent and make profit. As most genetic market is in the USA, which makes genetic research highly profitable, an inventor in India gets the opportunity of making profits using US patent domain. For example, a researcher in India working on genetically modified animals cannot get a patent in India as they are outside the scope of patent domain. However, he can get a patent in USA and make profits by licensing to US companies. His research in India over US patented genetically modified animals would not be hampered as they fall into the public domain in India. However, for an inventor or a company to take such an advantage, the inventor or the company should have the competence to get a patent and commercialize in USA and regulations for cross border technology transfer should be flexible. So, the broad public domain in India and broad patent domain in USA provides patent incentives

over genetic inventions for the Indian inventor from US Patent Law. So, the US Patent regime transcends beyond borders and helps in promoting the progress of genetic inventions in India. The role of US Patent Law to promote genetic research in India can be deduced from the 31 patents granted to Indian assignees on gene based inventions. Having said that, the benefits are limited to inventors or companies, which have the money and scale to reach the US market.

Despite the benefits offered by the differences in sizes of patent and public domains in USA and India, there are certain problems with such an incentive mechanism. As the incentives are derived from patents in USA and their commercialization in the US market, research in India would be directed to cater to the needs of US market. So, research will benefit USA more than India and there would not be enough research focus on gene problems specific to India. Furthermore, the advantage offered is limited to companies or inventors who have the financial and other resources to acquire patents and commercialize in USA. The advantage will not serve small players who might not have international reach. Most importantly, due to lack of internal incentives through a very narrow patent domain relating to gene-based inventions in India, there will not be much encouragement to indigenous research from internal sources. Due to a very wide public domain in India, free riding will carry on to a very large extent, destroying the incentives to research. If the broad US patent law could encourage research progress in India, a viable patent system suited for genetic inventions in India would help promote the progress of genetic research at a very rapid pace. The incentives from such a system would not only be accessible to all companies irrespective of size, economy and scale but would also be focused on problems and issues in India. In order to encourage optimal progress in gene related technology, a proper patent mechanism that would take advantage of diversity in sizes of patent and public domains without forgetting the need for providing patent

incentives to indigenous researchers has to be devised by the Indian government in place of the existing model.

Genetic Patent filter model for India

An appropriate genetic patent model based on a balance between patentability requirements and research exemptions that would provide internal patent incentives for Indian inventors and that would enable India to take benefit of the diversity in patent domains across the world will enable India to promote the progress of science and technology relating to genetics optimally. Patentability requirements and research exemptions are at two ends of the patent life cycle. While patentability requirements ensure grant of patents to worthy inventions, research exemptions ensure that the granted patent is not blocked arbitrarily from the public. Allowing the public to conduct research is as important as patent incentives through exclusivity in order to promote progress of science and technology. An imbalance between the scope of patentability requirements and scope of research exemptions would block progress of technology by either granting too many rights on the inventors or by granting too many rights to researchers. Both inventors and researchers should be given enough latitude to achieve optimal progress.

Broad patentability requirements with regard to gene based inventions and narrow research exemptions as is the case in USA would give too much leverage to patent holders as they will be able to get a patent easily and block others from using it for research purposes, thus blocking research and therefore slowing down the progress of genetic science. On the other hand, narrow patentability requirements for gene related inventions and very broad research exemptions as in India grants too much freedom to carry out research activities and nullifies the rights of the inventors, thus depriving the inventors of the incentives available from the patent system and therefore hampering progress of genetic research promoted by the patent regime. As the scope of

patentability requirements defines the size of patent domain and the scope of research exemptions defines the size of defacto public domain, the complication boils down to a balance between the size of patent and public domains. Apt changes in the patentability requirement and research exemption law of India would bring about the appropriate balance necessary to encourage best progress.

Some of the patentability requirements relating to gene based inventions and scope of research exemptions have to be modified suitably to promote rapid progress of genetic research in India. The patentability requirements that have to modified include patentable subject matter, utility, non-obviousness and enablement.

Patentable subject matter

The scope of patentable subject matter filter in India is very narrow and allows only a few gene related inventions to pass through it. It allows only gene sequences and genetically modified microorganisms to be eligible for the patent domain on satisfaction of other filters. Other genetic inventions such as genetically modified multicelluar organisms, gene therapies and so on are excluded from the scope of subject matter. Such a narrow filter blocks certain genetic inventions prima facie without putting them through the other filters. Such a policy would deprive Indian companies and researchers of incentives to invent and invest offered by the patent regime to the said genetic inventions. In order to provide them such incentives, the scope of patentable subject matter, which is a gate keeper requirement, should be broadened and the proscriptions against patentability of genetically modified multicelluar organisms and gene therapies should be removed. Such a broad filter would not block genetic inventions into the patent domain at the entry level and would subject them to patent grant based on satisfaction of other requirements.

Utility

The utility requirement relating to genetic inventions in India is very flexible. It allows all inventions that can be made and used in an Industry to pass through it. The only condition for satisfying the requirement is that the invention should be capable of being made, reproduced any number of times and used in any field. Any genetic invention would be capable of being made and reproduced and would be used in some way or the other in the biotech industry. As mentioned earlier in this chapter, even generic uses such as, uses as markers, promoters or probes, would be able to pass through the Indian utility requirement. Such a broad filter gives scope for inventions with meager or very insubstantial uses of non-specific nature to satisfy the requirement, thus giving scope for grant of patent to inventions having no use to the public. To allow only genetic inventions, which have worthy utility, the requirement has to be modified to include factors such as specific and substantial use to assess utility as under the US Patent Law. Such factors would ensure that unworthy genetic inventions or genetic inventions having meager uses for the public would not pass muster under this filter. It would also ensure that the burden of exclusive monopoly of a patent over the public would be worthy of usefulness of genetic invention to the public. It will also give an opportunity for the government to make a cost and benefit to public analysis before granting a patent.

Non-obviousness

The novelty filter is fine and can be left as it is. However, the non-obviousness filter in India gives rise to serious issues and should be modified. The existing non-obviousness requirement gives equal importance to technical advance and economic significance for satisfaction of the requirement. A genetic invention can be non-obvious if it is an advance over the existing science or if it has great economic significance. The concept of economic significance is totally against

the objectives of patent law to promote the progress of science because it makes it possible to technically grant patents over inventions that have no scientific advance but have economic significance. For example, if a method of isolating a gene is well-known and a scientist comes up with technique of using such method at a very low cost, his discovery would be eligible for a patent as it has great economic significance. Such a requirement shifs the focus of patent law and has the potential of impeding progress in genetic research by dragging inventions in the public domain into the patent domain. So, immediate steps have to be taken to remove the concept of economic significance in the non-obviousness requirement.

Furthermore, the level of a person with ordinary skill in non-obviousness determination in the art of genetics has to be kept at a medium level such as bachelors with experience or masters in genetic sciences. Such a person should be assumed to have good knowledge in his field of work or research for assessing non-obviousness. As the reasonable expectation of coming up with an invention will be assessed based on level of skilled person and his knowledge of the field the determination of non-obviousness would be quite certain. India has more human resources at the bachelors and masters level and high standards of requisite skill would not encourage creativity. Indian courts should learn from experiences in other countries and stringent standards should not be adapted in the beginning. The standards of obviousness can be strengthened as the field of genetics and related expertise matures.

Enablement

The enablement requirement is very broadly worded and has no explanation for genetic inventions in the manual of patents or in the patent rules. Such a situation gives rise to uncertainties and ambiguities, which act as impediments for progress of research. The requirement has been highly controversial in other countries and India has to learn from their experiences. If an inventor is

not aware of the standards of disclosure required of him, the experiments cannot be directed to requisite data and that might result in rejections based on lack of disclosure and enablement. To avoid such a situation the standards required for enablement have to be clearly specified. It would be a good idea to specify a separate written description and enablement requirement for genetic inventions as in USA. Written description will ensure that the inventor is in possession of the invention on the date of filing. Such a requirement is necessary considering the unpredictability of the field of genetics. And enablement will ensure that the invention is disclosed in such a manner that it can be carried out by a person with ordinary skill. The enablement requirement has to take into consideration undue experimentation and factors such as predictability of genetic field, level of skill and so on for making the determination. Spelling clear guidelines for enablement would drive away all ambiguities and will ensure that the public get full disclosure mandated by the patent law.

Research Exemptions

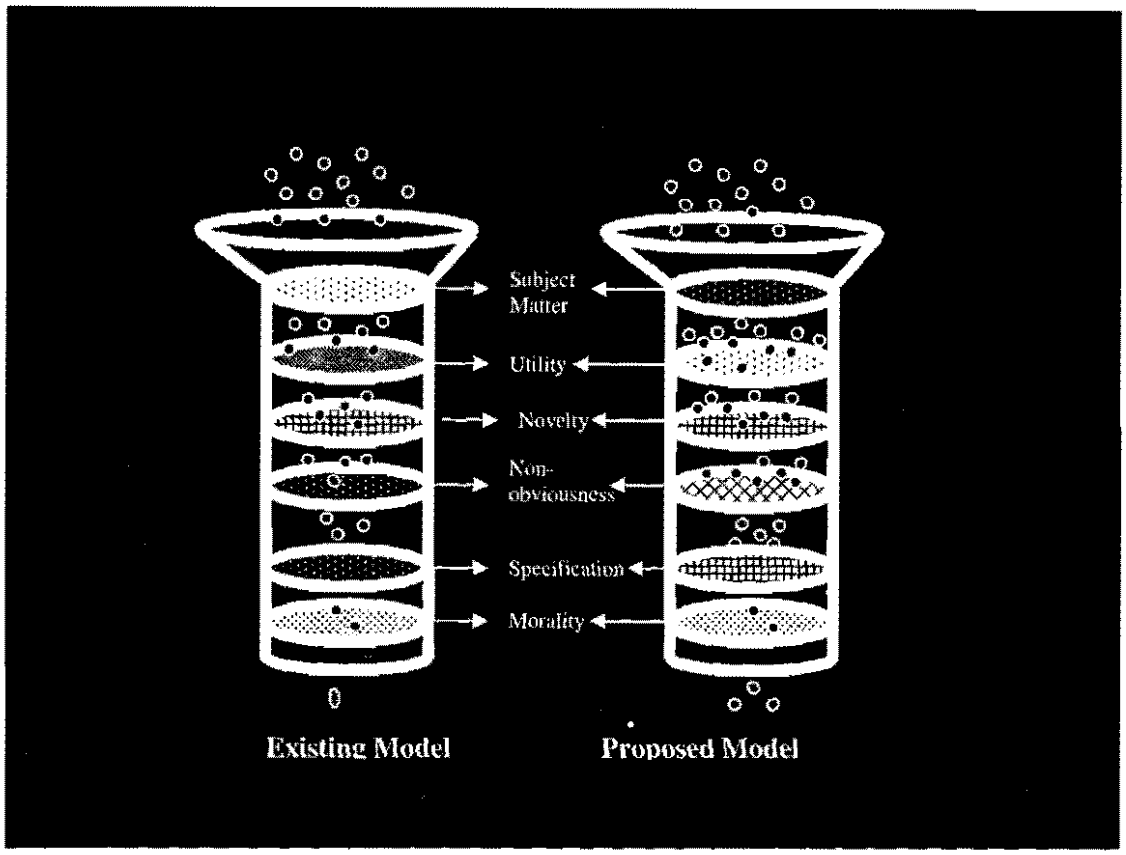
With regard to research exemptions, the Indian patent law allows a researcher to use the patented invention for research or experiment or education to pupils and for purposes of getting approval from a government agency. The scope of the exemption is too broad and creates a very wide public domain, thus allowing the researcher to make use of the patented invention in a variety of ways as long as it is research or experiment or education without any liability. Such a broad scope of research exemptions would take away the incentives offered by the patent regime because an inventor would not be interested in acquiring a patent, which would any way be available for free to one and all in the form of broad research exemptions. Such a scenario is very fatal to gene technologies as research involves huge expenditure and has a very long gestation period. So, the scope of research exemptions should be narrowed to include only experimental or research or educational activities that are not

commercial in nature. The extent of commercial aspects to be considered in determining research exemptions have to be clearly specified. They should not exclude any type of activities such as activities of academic institutions or government research institutes as in USA. On the other hand research exemptions should not be as broad as in India now. A middle path has to be taken between the two extremes. Furthermore, the exemption relating activities for obtaining government approval should be limited to activities directly related to obtaining drug approval as opposed to encompassing all inventions, as it exists now.

To conclude, the best genetic patent model for India would be genetic patentability requirements having a broad patentable subject matter, narrow utility, narrow non-obviousness, well-defined enablement and narrow research exemptions. Such a model will bring about proper balance between patent and public domains by providing patent incentives for inventors and investors and by ensuring that the patented genetic inventions will not be subject to free riding without liability. Such a model will provide proper internal incentives to promote progress of gene technology within India, without losing sight of the needs specific to India. That will also enable Indian companies and inventors to utilize diversity in patent laws for commercial benefit.

The proposed patentability requirements are illustrated in the figure below. The figure compares the existing patentability filter configuration with the proposed configuration.

Figure 11.3



The proposed configuration would have the effect of encouraging progress of gene-based inventions by coining a broader subject matter, narrow utility, by strengthening the non-obviousness filter and by defining the enablement requirement for genetic inventions. Such a configuration would enable all gene-based inventions to pass through subject matter, thus removing the problem with blanket ban on certain sub-fields and by subjecting them to scrutiny of other filters to determine their worthiness in the broader perspective of promoting progress in gene technology. The broad subject matter filter relating to genetic inventions will ensure that all genetic inventions pass through the entry and that they will be subject to other requirements without discrimination based on the subject. The stringent utility requirement will test the specific and substantial usefulness of the genetic invention to the public. If a genetic invention does not have any worthy use or proposes generic uses, it will be weeded out at this stage. For example, this

The size off public and patent domain in a country depends on different factors incorporated within its patent law. Chapters 4 to 9 elucidate the variation in sizes of public and patent domain of gene based inventions in US, Europe and India due to differences in the constitution of patentability and morality requirements. Furthermore, Chapter 10 elucidates the differences in scope of research exemptions and its impact on sizes of public domain with regard to genetic inventions in each country/region. The differences in constitution of requirements and research exemptions can be attributed to the divergence in development level and social, economic and ideological conditions in those countries/regions. As the ideal configuration of each requirement that would promote utmost progress in genetics varies from country to country based on various conditions, it is not possible to define a utopian balance between all requirements that would work for all countries and the ideal configuration of each requirement to promote optimal progress of science differs from country to country. With this limitation in mind, this chapter points out the problems with existing configuration of requirements in India and proposes a solution in the form of a model that balances the size of patentability requirements with the size of research exemptions for promoting rapid progress of genetic science. The model proposed in this chapter is one way of solving problems arising out of diversity and can be used in combination with other solutions.

Patent/public domain Variance

Each of the requirements has differential treatment in different countries/regions with regard to genetic inventions. The scope of subject matter requirement is broad in USA, narrow in India and moderate in Europe. While all gene based inventions except human beings would pass through the subject matter filter in USA, genetically modified multicellular organisms, human beings and gene therapies are not patentable in India and genetically modified nonmamalian multicellular organisms, human beings and gene therapies are not patentable in Europe. The subject matter filter, which is the

patentability model would bring about a balance between patent and public domain in gene based inventions that would ensure optimal advancement of genetic science.

Furthermore, as a patent granted in one country would fall into the public domain of another country unless a patent is obtained in the first country, inventors in India would be able to take benefit of patents granted in USA, Europe or in any other country without liability. As they have the option of obtaining patents in USA and other developed countries, they can utilize such an option to obtain commercial benefit through such patents. If the patent holder in other countries obtains a patent in India, the Indian researcher can still make use of the research exemptions to conduct research and develop the invention. So, the proposed genetic patent model would encourage progress of gene technology by providing incentives from both internal and external patent regimes.

Annexure - I

PART - I

DATABASE INFORMATION

USPTO - PATENT FULL TEXT DATABASE

Knowledge of the structure and contents of a database enables a person to search the database efficiently. The US Patent full text database contains all US patents from 1790 to the present issue week. Full text of patents from January 1976 to present is available for search. All felids on the document such as title, abstract, classification, inventor's name, assignee's name, etc. can be searched. Patents from 1790 to December 1975 can be searched only by patent number and current US Classification. However, images of the full patent document are available. Data on published applications is available on the database from March 15th, 2001 till date. The database is generally updated every Tuesday, the day on which patents are issued at the USPTO.

Publication Site for Issued and Published Sequences (PSIPS):

The PSIPS web site provides Sequence Listings, tables, and other mega items for granted US patents or published US patent applications. All sequences and tables for listed patents or publications are available for viewing, without downloading, by accessing the proper document detail page and then submitting a SEQ ID NO or a mega table ID number. PSIP system acts as a storage and retrieval site for Sequence Listings that are at least 300 pages (roughly 600Kb), mega table sections that are at least 200 contiguous pages, and other mega items. The data have been included in either a granted US patent or a published US patent application. Shorter Sequence Listings and tables are accessible via Patents-, and Applications-, on-the-Web home pages. PSIPS can be used to view or download individual sequences or tables, entire Sequence Listing, mega table section, or other mega item. Documents on the

PSIPS page can be accessed by entering the Document Id. or the Patent Number or by looking at all documents stored by PSIPS. The sequence downloaded from PSIPS can be entered into a sequence-searching site in order to search for sequences.

Source: USPTO website www.uspto.gov

ESP@CENET - WORLD WIDE DATABASE

The Worldwide database enables to search for information about published patent applications from over 70 different countries and regions. It is based on the PCT minimum documentation, which is defined by WIPO as the minimum requirement for patent collections used to search for prior-art documents for the purpose of assessing novelty and inventiveness. The EPO has expanded the coverage of its internal database far beyond the PCT minimum documentation to include data from other countries and other time periods. Moreover, additional information, such as ECLA symbols and references to cited documents, is added to other fields by examiners in the course of their work. In January 2004, esp@cenet held data on 45 million patents from 71 countries. A total of 24.2 million of these patents have a title, while 18.3 million have an ECLA class and 7.1 million an abstract in English.

Source: European patent office database www.ep.espacenet.com visited on 21st September 2005.

PART - II

INTERNATIONAL CLASSIFICATION DEFINITIONS - Biotech Patents

A01H1/00 -Processes for modifying genotypes.

A01H4/00- Plant reproduction by tissue culture techniques.

A61K38/00- Medicinal preparations containing peptides (peptides containing beta-lactam rings A61K 31/00; cyclic dipeptides not having in their molecule any other peptide link than those which form their ring, e.g. piperazine-2,5-diones, A61K 31/00; ergoline-based peptides A61K 31/48; containing macromolecular compounds having statistically distributed amino acid units A61K 31/74; medicinal preparations containing antigens or antibodies A61K 39/00; medicinal preparations characterized by the non-active ingredients, e.g. peptides as drug carriers,.A61K 47/00).

A61K39/00- Medicinal preparations containing antigens or antibodies (materials for immunoassay G01N 33/53) .

A61K48/00- Medicinal preparations containing genetic material, which is inserted into cells of the living body to treat genetic diseases; Gene therapy.

C02F3/34- characterised by the micro-organisms used.

C07G11/00- Antibiotics.

C07G13/00- Vitamins (vitamin K_1 C07C 50/14; pantothenic acid C07C 235/12; vitamins of the D group C07C 401/00; vitamin A C07C 403/00; pyridoxal, pyridoxamin C07D 213/66; pyridoxin C07D 213/67; vitamin C C07D 307/62; tocopherols C07D 311/72; lipoic acid C07D 339/04; vitamin B_1 C07D 415/00; riboflavin C07D 475/14; biotin C07D 495/04; sideramines, corresponding desferri compounds C07F 15/03; vitamin B_{12} C07H 23/00).

C07G15/00- Hormones.

C07K4/00- Peptides having up to 20 amino acids in an undefined or only partially defined sequence; Derivatives thereof .

C07K14/00- Peptides having more than 20 amino acids; Gastrins; Somatostatins; Melanotropins; Derivatives thereof.

C07K16/00- Immunoglobulins, e.g. monoclonal or polyclonal antibodies.

C07K17/00- Carrier-bound or immobilised peptides (carrier-bound or immobilised enzymes C12N 11/00); Preparation thereof.

C07K19/00- Hybrid peptides.

C12M - APPARATUS FOR ENZYMOLOGY OR MICROBIOLOGY (installations for fermenting manure A01C 3/02; preservation of living parts of humans or animals A01N 1/02; physical or chemical apparatus in general B01; brewing apparatus C12C; fermentation apparatus for wine C12G; apparatus for preparing vinegar C12J 1/10).

C12N- MICRO-ORGANISMS OR ENZYMES; COMPOSITIONS THEREOF (biocides, pest repellants or attractants, or plant growth regulators containing micro-organisms, viruses, microbial fungi, enzymes, fermentates, or substances produced by, or extracted from, micro-organisms or animal material A01N 63/00; food compositions A21, A23; medicinal preparations A61K; chemical aspects of, or use of materials for, bandages, dressings, absorbent pads or surgical articles A61L; fertilisers C05); PROPAGATING, PRESERVING, OR MAINTAINING MICRO-ORGANISMS (preservation of living parts of humans or animals A01N 1/02); MUTATION OR GENETIC ENGINEERING; CULTURE MEDIA (microbiological testing media C12Q).

C12P- FERMENTATION OR ENZYME-USING PROCESSES TO SYNTHESISE A DESIRED CHEMICAL COMPOUND OR COMPOSITION OR TO SEPARATE OPTICAL ISOMERS

FROM A RACEMIC MIXTURE (fermentation processes to form a food composition A21, A23; compounds in general, see the relevant compound class, e.g. C01, C07; brewing of beer C12C; producing vinegar C12J; processes for producing enzymes C12N 9/00; DNA or RNA concerning genetic engineering, vectors, e.g. plasmids, or their isolation, preparation or purification C12N 15/00).

C12Q- MEASURING OR TESTING PROCESSES INVOLVING ENZYMES OR MICRO-ORGANISMS (immunoassay G01N 33/53); COMPOSITIONS OR TEST PAPERS THEREFOR; PROCESSES OF PREPARING SUCH COMPOSITIONS; CONDITION-RESPONSIVE CONTROL IN MICROBIOLOGICAL OR ENZYMOLOGICAL PROCESSES.

C12S- PROCESSES USING ENZYMES OR MICRO-ORGANISMS TO LIBERATE, SEPARATE OR PURIFY A PRE-EXISTING COMPOUND OR COMPOSITION (biological treatment of water, waste water, or sewage C02F 3/00, of sludge C02F 11/02; processes using enzymes or micro-organisms to separate optical isomers from a racemic mixture C12P 41/00); PROCESSES USING ENZYMES OR MICRO-ORGANISMS TO TREAT TEXTILES OR TO CLEAN SOLID SURFACES OF MATERIALS.

G01N27/327- Biochemical electrodes.

G01N33/53 - Immunoassay; Biospecific binding assay; Materials therefor (medicinal preparations containing antigens or antibodies A61K; haptens in general, see the relevant places in class C07; peptides, e.g. proteins, in general C07K).

G01N33/54- Double or second antibody.

G01N33/55- the carrier being inorganic.

G01N33/57- using kinetic measurement, i.e. time rate of progress of an antigen-antibody interaction.

G01N33/68- involving proteins, peptides or amino acids.

G01N33/74- involving hormones.

G01N33/76- Human chorionic gonadotropin.

G01N33/78- Thyroid gland hormones.

G01N33/88- involving prostaglandins.

G01N33/92- involving lipids, e.g. cholesterol.

Source: World Intellectual Property website http://www.wipo.int/classifications.

PART - III

BIOTECH PATENTS TO INDIAN APPLICANTS

S.NO.	NAME OF THE COMPANY/INSTITUTE	NO. OF BIOTECH PATENTS	MEDICAL BIOTECH PATENTS
1	CSIR	109	85
2	HOECHST INDIA	22	0
3	LEVER HINDUSTAN LTD	16	13
4	ASTRA RES CT INDIA	12	4
5	HINDUSTAN ANTIBIOTICS LIMITED	10	4
6	NAT INST IMMUNOLOGY	9	6
7	AGHARKAR RES INST	5	1
8	BIOCON INDIA LTD	4	2
9	IIT INDIAN INST OF TECHNOLOGY	4	3
10	OSMANIA UNIVERSITY (IN)	4	0
11	BAYER AG	3	2
12	DEPARTMENT OF SCIENCE AND TECHNOLOGY	3	2
13	JANA NANIGOPAL	3	3
14	KOPRAN LTD	3	1
15	NAT RES DEV	3	3
16	NOVOZYMES AS	3	3
17	PFIZER	3	0
18	SOUTHERN PETROCHEMICAL IND COR	3	0
19	SHANTHA BIOTECHNICS PVT LTD (IN)	3	2
20	AGRACETUS	2	0
21	ARVIND PURUSHOTTAM JOSHI; KALPANA JOSHI	2	2
22	BHATTACHARYA CHANDRA BHAIRAB	2	2
23	CHETANA VAISHNAVI	2	2

S.NO.	NAME OF THE COMPANY/INSTITUTE	NO. OF BIOTECH PATENTS	MEDICAL BIOTECH PATENTS
24	FRAPPIER ARMAND INST	2	0
25	IIT BOMBAY	2	2
26	INDIAN COUNCIL OF MEDICAL RES (IN)	2	2
27	KERNFORSCHUNGSANLAGE JUELICH	2	1
28	LEPETIT SPA	2	0
29	LUPIN LAB LTD	2	1
30	M S THEMIS CHEMICAL LTD (IN)	2	0
31	PFIZER PROD INC	2	1
32	PHILLIPS PETROLEUM CO	2	2
33	POLITECHNIKA GDANSKA	2	0
34	REDDI OJILA SUNDARARAMA (IN); SHARMA KRISTAPATI RAMA (IN)	2	1
35	THAPAR CORP RESEARCH AND DEV	2	1
36	TEA RES ASS (IN)	2	2
37	UNIV EMORY	2	2
38	UNIV DELHI SOUTH CAMPUS	2	2
39	ALEMBIC CHEMICAL WORKS CO LTD	1	0
40	ALL INDIA INST MED (IN)	1	0
41	ALTUS BIOLOG INC	1	1
42	ANEJA RAM PRAKASH AND NATIONAL	1	1
43	ASAHI CHEMICAL IND	1	0
44	ASTA PHARMA AG	1	1
45	BALIKARAN PAL RAMPRASAD DR (IN)	1	1
46	BEECHAM GROUP LTD	1	0
47	BHABHA ATOMIC RES CT (IN)	1	0
48	BHATNAGAR RAKESH; WAHEED SYED MOHSIN; (+1)	1	1

S.NO.	NAME OF THE COMPANY/INSTITUTE	NO. OF BIOTECH PATENTS	MEDICAL BIOTECH PATENTS
49	BIOTEST PHARMA GMBH	1	1
50	BORYUNG BIOPHARMA CO	1	1
51	BURNS PHILP INDIA LTD	1	1
52	CITURGIA BIOCHEMICALS LTD	1	0
53	DEFENCE RES & DEV ORGANISATION (IN)	1	1
54	DEPT OF ATOMIC ENERGY	1	0
55	DEPT OF BIOTECHNOLOGY MINISTRY	1	1
56	DIMMINACO AG	1	1
57	DIRECTOR GENERAL INDIAN COUNCI	1	0
58	ESVIN ADVANCED TECHNOLOGIES LT (IN)	1	0
59	FIDIA SPA	1	1
60	G B PANT UNIVERSITY OF AGRICUL	1	1
61	GANESAN KALIANNAN (IN); BANERJEE ANASUA; (+1)	1	1
62	GENESIS RES & DEV CORP LTD	1	1
63	GUJARAT STATE FERTILIZERS CO L	1	0
64	HIDEAJI YAMADA; NITTO CHEMICAL INDUSTRY CO LTD	1	1
65	HODES DAVID S; LEIDY GRACE; (+2)	1	0
66	ICI INDIA LTD (IN)	1	0
67	IMMUNOMEDICS INC	1	1
68	INDIAN INST OF SCIENCE LAB OF (IN); VITTAL MALLYA SCIENT RES FOUND (IN)	1	1
69	INDIAN INST OF SCIENCE MOLECUL (IN)	1	1
70	INDIAN JUTE IND RES	1	0
71	INGROLE NEETA BHAUSAHEB (IN)	1	0
72	INST MERIEUS	1	1
73	INST OF IMMUNOHAEMATOLOGY	1	1

S.NO.	NAME OF THE COMPANY/INSTITUTE	NO. OF BIOTECH PATENTS	MEDICAL BIOTECH PATENTS
74	JAPAN TOBACCO INC	1	1
75	KRISHNENDU ACHARYA; RUPA ACHARYA	1	1
76	KUMAR ASHOK; KUMAR PRITI	1	1
77	LEPETIT G SPA; PARENTI F; (+3)	1	0
78	LILLY CO ELI	1	0
79	MALADKAR NEELKANTH KESHAV DR (IN); MALADKAR SAMIR NEELKANTH (IN)	1	0
80	MEDICINSKA AKADEMIA PRESIDENCY	1	1
81	MICROBIAL CHEM RES FOUND	1	0
82	MODAK SOHAN PRABHAKAR DR (IN); GUIGNET JEAN DANIAL (CH)	1	1
83	MUKHERJEE JIBANANDA (IN)	1	1
84	MUKHERJEE KRISHNA JYOTI DR (IN); YAZDANI SYED SHAMS (IN)	1	1
85	NACIONAL DE BIOPREPARADOS CENT	1	1
86	NALCO CHEMICAL CO	1	0
87	NAT INST OF HEALTH & FAMILY WE (IN)	1	0
88	NAT INST OF VIROLOGY	1	0
89	NORTH AMERICAN VACCINE INC	1	1
90	PARAB PRADEEP BHASKAR	1	1
91	PASTEUR VACCINS	1	1
92	PHYSIC TECHNOLOGIES PVT LTD (IN)	1	1
93	PRAJ COUNSELTECH PVT LTD	1	1
94	PRAJ IND LTD (IN)	1	1
95	PROALGEN BIOTECH LTD	1	1
96	R M D CRYSTAL RES PVT LTD (IN)	1	1
97	RAO K KOTESWARA DR (IN)	1	1

S.NO.	NAME OF THE COMPANY/INSTITUTE	NO. OF BIOTECH PATENTS	MEDICAL BIOTECH PATENTS
98	RAY PRASANTA KUMAR PROF (IN); MODAK DEBA PRASAD DR (IN); (+4)	1	0
99	RICAN LTD	1	1
100	SANRAKU OCEAN CO; PANLABS INC	1	0
101	SANTANU ROY (IN)	1	0
102	SREE CHITRA TIRUNAL INST FOR M (IN)	1	1
103	SECR DEFENCE BRIT	1	1
104	SECRETARY DEPT OF BIOTECHNOLOG; UNIV HYDERABAD	1	1
105	SUN PHARMACEUTICAL IND LTD	1	0
106	SEAGRAM MFG LTD	1	1
107	TOPICAL BOTAN GARDEN AND RES I (IN)	1	0
108	TATA INTERNAT LTD	1	1
109	UCB SA	1	0
111	VINOD BABURAO SHIDHAM DR; MRS ANJANI VINOD SHIDHAM	1	1
112	VITTAL MALLYA SCIENT RES FOUND (IN)	1	0
	TOTAL	333	202

Annexure - II

Genetic Patents - Indian Assignees

Sl.No	Title	Assignee	USA	Europe	India
1	Method for enhancing foreign gene expression in baculovirus expression vector system	National Institute of Immunology	Granted		
2	Process for identifying mutagens and antimutagens	CSIR	Granted		Filed
3	Process for the preparation of semisynthetic amplicon useful for sex determination of the papaya plant	CSIR	Granted		
4	Mycobacterium tuberculosis specific DNA fragment	CSIR	Granted	Granted	
5	Process for simultaneous preparation of sex specific and gender-neutral semisynthetic amplicons useful for sex determination	CSIR	Granted		
6	Mycobacterium tuberculosis specific DNA fragment	CSIR	Granted	Granted	
7	Bicistronic DNA construct comprising X-myc transgene for use in production of transgenic animal model systems for human hepatocellular carcinoma and transgenic animal model systems so produced	National Institute of Immunology	Granted		
8	Species specific DNA sequences and their utilization in identification of viola species and authentication of "banafsha" by polymerase chain reaction	CSIR	Granted		
9	Vitamin B12 --biodegradable micro particulate conjugate carrier systems for peroral delivery of drugs, therapeutic peptides/proteins and vaccines	CSIR	Granted	Granted	Filed
10	DNA markers for assessing seed purity and method of using DNA sequences for assessing seed purity	CSIR	Granted		

Sl.No	Title	Assignee	USA	Europe	India
11	DNA markers for assessing seed purity and method of using DNA sequences for assessing seed purity	CSIR	Granted	Filed	
12	Methyl analogs of simvastatin as novel HMG-CoA reductase inhibitors	Ranbaxy Laboratories Limited	Granted		
13	Method for detecting a single nucleotide polymorphism in p21waf1/cip1 gene as an indicator of risk of esophageal cancer	CSIR	Granted		
14	Method of detection of allelic variants of SCA2 gene	CSIR	Granted		
15	Use of drosophila melanogaster as a model for screening psychostimulant plant materials	CSIR	Granted		
16	Oligonucleotide primers for phosphotidyl inositol in bacillus cereus	CSIR	Granted		
17	Screening the activity of drugs for central nervous system (CNS)	CSIR	Granted		
18	Primers for screening schizophrenia and a method thereof	CSIR	Granted	Filed	
19	Cost effective method for selective methylation of erythromycin A derivatives	Ranbaxy Laboratories Limited	Granted	Granted	
20	Species specific DNA sequences and their utilization in identification of viola species and authentication of "banafsha" by polymerase chain reaction	CSIR	Granted		
21	Polypeptides of covalently linked synthetic bioactive peptide analog(s) for treatment of cancer	Dabur Research Foundation	Granted		
22	Chimeric protein .alpha. BNAC crystallin with extraordinarily high chaperone-like activity and a method related to the use thereof	CSIR	Granted		

Sl.No	Title	Assignee	USA	Europe	India
23	Bombesin analogs for treatment of cancer	Dabur Research Foundation	Granted	Filed	
24	Process for production of the somatostatin analog, octreotide	Wockhardt Limited	Granted	Granted	Filed
25	Chimeric cry1E .delta.endotoxin and methods of controlling insects	CSIR	Granted	Filed	
26	Skeletal cell model to screen anti-diabetic compounds	CSIR	Granted		Filed
27	Oligonucleotide primers having SEQ ID NOs. 1 to 21 and a process for detection of parasite Salmonella using oligonucleotide primers	CSIR	Granted	Filed	
28	Growth of human Mesenchymal Stem Cells (hMSC) using umbilical cord blood serum and the method for the preparation thereof	Reliance Life Sciences Pvt. Ltd.	Granted		
29	HMG CoA-reductase inhibitors	Ranbaxy Laboratories Limited	Granted	Filed	Filed
30	Two gonadotropin releasing hormones and a method to isolate the same	CSIR	Granted	Filed	Filed
31	Process for proliferation and differentiation of rat ascinar cells	CSIR	Granted		

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