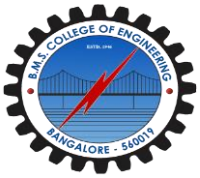

B.M.S. COLLEGE OF ENGINEERING, BANGALORE – 560019
(Autonomous College affiliated to VTU)

Department of Biotechnology

IPR REPORT

Resource person: **Dr. Sarasija Padmanabhan**

Course Coordinator : **Dr Rashmi S Shenoy**

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6	**Patent strategies(Continued)**
7	**Case study presentations-understanding of the patent laws.**
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IPR (Intellectual Property Rights) Report-Session 1

DEPARTMENT OF BIOTECHNOLOGY

Course Title	INTELLECTUAL PROPERTY RIGHTS										Credits	0			
Course Code	1	9	B	T	6	N	C	I	P	R	L-T-P-S	0	0	0	0

COURSE PRE-REQUISITES: Microbiology, Basics of biomolecules, Biochemistry, Genetic engineering, Bio analytical techniques,

COURSE DESCRIPTION: IPR syllabus in the curriculum emphasize on the legal aspects of intellectual properties. It provides an insight into the monopoly rights conferred to an inventor for the development of innovative processes and products. The course also includes legal perspectives of biotechnological inventions preferably products and processes of genetic modification.

COURSE OBJECTIVES: The course imparts in depth knowledge about intellectual property rights, its types, differences and uses. The students will be exposed to patent drafting, analyzing and comparing with case studies. The course provides essential information to students about the exploration of IP into the field of biotechnology sector with relevant case studies.

Date :23rd May,2022.

Time: 12:00 P.M to 1:00 P.M

Venue: BT classroom 4

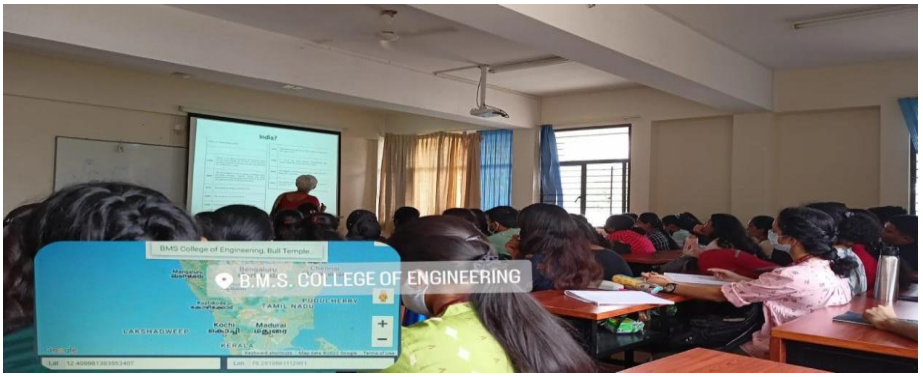
Speaker: Dr. Sarasija Padmanabhan, Patent Consultant, Indian Institute of Science Campus, India.

Session 1: Introduction to IPR

The session started with introduction to Intellectual Property Rights, where students were asked to mention words that come to their minds about IPR. Some as mentioned by the students were: Something we have rights over, copyright for some kind of creation, plagiarism, trademarks, patents etc. If its Biotechnology domain, the copyright would come in for Research papers. Later the speaker introduced to the history of subject, the laws of Great Britain. Most of which started in Europe where Antiquity: Inventions happened long ago to solve certain problems. An example was given, where the wheel initially was not invented keeping transportation in mind, it was discovered for use in pottery. The session later on proceeded with details on the historical laws, trades and regimens with respect to various countries like China, India, Italy, Germany, France, Holland and Belgium. As in China, Salt had a monopoly (exclusive right). Someone owns trade of salt, therefore only one person can sell it. This took place sometime during the Ming Dynasty when someone figured salt was very important. If there was a patent, then there was a monopoly for 20 years from the day of filament. Then there was also trade secret which was passed on from parents to children and since it has no association with the Government, it has no guarantee. Further, the session continued with introducing the dark ages – where the arts of Greece and Rome disappeared of which a little bit of information was preserved in the Eastern Empire of Byzatine .

In Italy, Farming was very important and so if farming went well they were given gifts such as lands. Similarly, the speaker explained several examples on how the Patents were initiated in other countries. The session ended by emphasing on statue of Monopolies where people work, serve others and pay taxes and how it changed with patents. There were total of 60 students from Department of Biotechnology and 10 students from Medical Electronics, B.M.S College of Engineering, Bangalore, who participated in the session and were very intrigued by the course module.

Gallery :



IPR(Intellectual Property Rights) Report-Session 2

DEPARTMENT OF BIOTECHNOLOGY

Course Title	INTELLECTUAL PROPERTY RIGHTS										Credits	0			
Course Code	1	9	B	T	6	N	C	I	P	R	L-T-P-S	0	0	0	0

COURSE PRE-REQUISITES: Microbiology, Basics of biomolecules, Biochemistry, Genetic engineering, Bio analytical techniques,

COURSE DESCRIPTION: IPR syllabus in the curriculum emphasize on the legal aspects of intellectual properties. It provides an insight into the monopoly rights conferred to an inventor for the development of innovative processes and products. The course also includes legal perspectives of biotechnological inventions preferably products and processes of genetic modification.

COURSE OBJECTIVES: The course imparts in depth knowledge about intellectual property rights, its types, differences and uses. The students will be exposed to patent drafting, analyzing and comparing with case studies. The course provides essential information to students about the exploration of IP into the field of biotechnology sector with relevant case studies.

Date :3rd June ,2022.

Time:2.00-4.00PM

Venue: BT classroom 3

Speaker: Dr. Sarasija Padmanabhan, Patent Consultant, Indian Institute of Science Campus, India.

Session 2: Introduction to IPR-Continued

The session started with in depth understanding of Intellectual Property Rights with respect to various types like Trademarks, Geographical Implications, Copyrights, Patents, Trade secret, Industrial Design (duration 10 years), Protection of Plant Variety and farmers Rights. The speaker then explained the basic difference where Property is Tangible and how Tangible can be further classified into movable and Immovable. Intangible canbe classified into lease Security, Emotional Goodwill and Intellectual. An Intellectual property cannot be touched or felt and is of a Form which is protectable. e.g. Patents. The session continued by familiarizing the students with various treaties and reciprocal agreements like Paris Convention, World Convention, WTO and TRIPS. There was a

reasoning given for the basis for IP protection and who owns the patent. The session ended by explaining what can be patentable and what are the specific exclusions with respect to patent. All the students enjoyed the session and gave positive remarks on the session

Gallery:

GPS Map Camera
Bengaluru, Karnataka, India
First floor ,New, BMS COLLEGE OF ENGINEERING, Basavanagudi, Bengaluru, Karnataka 560019, India
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BMS College

GPS Map Camera
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BMS College

Attendees:

Attendees- Biotechnology Department (03/06/2022)

S.NO.	USN	NAME	Signature
1	1BM18BT024	KEERTHANA M	
2	1BM18BT031	NAMRATHA V	
3	1BM18BT051	SRIRAKSHA A NADIG	
4	1BM19BT001	ADITI P ARAKERI	
5	1BM19BT002	ADITI S	
6	1BM19BT004	AMISHA M SHET	
7	1BM19BT006	ANKITA SREEKUMAR	
8	1BM19BT007	ANOKSHA BHATTACHARJEE	
9	1BM19BT008	ANUPRIYA MITRA	
10	1BM19BT009	BHARGAVI	
11	1BM19BT010	C.POOJA	
12	1BM19BT011	DEEKSHA M	
13	1BM19BT013	EASHA RATHNAMALA	
14	1BM19BT014	EVANGELINE LYDIA C	
15	1BM19BT015	GRISHMA RAJA	
16	1BM19BT016	H SANJANA RAJENDRA	
17	1BM19BT017	HANEEFA TASNEEM SHAIK	
18	1BM19BT019	J SAHANA	
19	1BM19BT020	JOTHIKA K	
20	1BM19BT021	JYOTHI BAI V	
21	1BM19BT023	KAVYA B R	
22	1BM19BT024	L.AYUSH	
23	1BM19BT026	MEGHANA B V	
24	1BM19BT027	NANDHINI M	
25	1BM19BT028	NANDINI.M.NAIK	
26	1BM19BT029	NEHA HS	
27	1BM19BT030	NEHA KUMARI R	
28	1BM19BT031	NIDHI P MANIYAL	
29	1BM19BT032	NIHARIKA A	
30	1BM19BT033	NISCHALA SATISH BABU	
31	1BM19BT034	PAVITHRA HEMANTH KUMAR	
32	1BM19BT035	POOJA V C	
33	1BM19BT036	PRATEEKSHA SANTHOSH	
34	1BM19BT037	RAM MANAS N	
35	1BM19BT038	RAMYA V	
36	1BM19BT039	RITHIKA ANAND	
37	1BM19BT040	RITHIKA V NAYAK	
38	1BM19BT041	RUCHITHA D U	
39	1BM19BT042	SAHANA MOULIC	
40	1BM19BT043	SAMHITA D RAO	
41	1BM19BT044	SANJEEVINI.A.S	
42	1BM19BT045	SHAHEDA NOOR	
43	1BM19BT046	SHAKTHI KRISHNAMURTHY	
44	1BM19BT048	SHIVADARSHANA	
45	1BM19BT049	SHIVANGI V DESHPANDE	
46	1BM19BT050	SHIVARAJA B	
47	1BM19BT051	SUHAS SREEHARI	
48	1BM19BT052	SURABHI V	
49	1BM19BT053	SURABHI.V	
50	1BM19BT056	TEJASHREE .D	
51	1BM19BT057	TEJASWINI V JATTI	
52	1BM19BT059	V SOUMYA	
53	1BM19BT060	VIDHI D JAIN	
54	1BM19BT061	VYSHALI CP	
55	1BM19BT062	NISHCHITHA JAGADEESH	
56	1BM19BT063	ASHRITA NIHARIKA ASHWIN	
57	1BM19BT064	DHAIVAT TRIVEDI	
58	1BM19BT065	HRISHIKESH RAJESH	
59	1BM19BT066	PRAKASH SUBEDI	
60	1BM19BT067	SAI MADHUVANTHY	
61	1BM19BT068	SNEHA GOPINATH PUTHIYANDI	
62	1BM19BT069	SREEVIPANCHIKA	
63	1BM18BT005	ANKITHA SREE BABU	
64	1BM18BT021	JNANA PONNAMMA K P	

IPR(Intellectual Property Rights) Report-Session 3

DEPARTMENT OF BIOTECHNOLOGY

Course Title	INTELLECTUAL PROPERTY RIGHTS										Credits	0			
Course Code	1	9	B	T	6	N	C	I	P	R	L-T-P-S	0	0	0	0

COURSE PRE-REQUISITES: Microbiology, Basics of biomolecules, Biochemistry, Genetic engineering, Bio analytical techniques,

COURSE DESCRIPTION: IPR syllabus in the curriculum emphasize on the legal aspects of intellectual properties. It provides an insight into the monopoly rights conferred to an inventor for the development of innovative processes and products. The course also includes legal perspectives of biotechnological inventions preferably products and processes of genetic modification.

COURSE OBJECTIVES: The course imparts in depth knowledge about intellectual property rights, its types, differences and uses. The students will be exposed to patent drafting, analyzing and comparing with case studies. The course provides essential information to students about the exploration of IP into the field of biotechnology sector with relevant case studies.

Date :6th June ,2022.

Time: 12:00p.m to 1: 00p.m

Venue: BT classroom 3

Speaker: Dr. Sarasija Padmanabhan,Patent Consultant ,Indian Institute of Science Campus ,India.

Session 3: **Scope of Patentability under the Patent Act**

The speaker started the session by introducing the students on Indian Patent Act sec 2(1)(I) and invention. She emphasised that Patent laws are not uniform. If you need to get a patent, you need to know the legalities.'New 'invention shouldn't be there in prior art e.g If making a wheel, even care painting of the wheel can be prior art. Few examples were given with respect to certain disciplines like; in Bioinfomatics discipline, the information obtained through Blast can't be patented. New form of known substance is not patentable if it does not increase the efficacy of old substance. If enhanced efficacy is proved it is patentable. Few more examples were given to students for better understanding of innovations that can/cannot be patentable. No patents on methods of horticulture or Agriculture, patents can be considered for devices.E.g. cultivation of Algae. Medicinal, Therapeutic processes for humans, animals etc. cannot be patented. A disease is not Patentable. It could be coupled with a device and made patentable.E.g. Cancer cells –No but a laser knife to remove cancer cells –Yes. Mathematical, business method etc. cannot be patented.E.g. If you have an app you can put that in a device and patent that device. Presentation of information can be subjected to copyright but not patent.E.g. Arranging something in a dictionary. The session ended by concluding that every country has different laws and

regulations with respect to patenting. All the students were intrigued with the talk and gave good feedback on the session.

Gallery:

IPR(Intellectual Property Rights) Report-Session 4

DEPARTMENT OF BIOTECHNOLOGY

Course Title	INTELLECTUAL PROPERTY RIGHTS										Credits	0			
Course Code	1	9	B	T	6	N	C	I	P	R	L-T-P-S	0	0	0	0

COURSE PRE-REQUISITES: Microbiology, Basics of biomolecules, Biochemistry, Genetic engineering, Bio analytical techniques,

COURSE DESCRIPTION: IPR syllabus in the curriculum emphasize on the legal aspects of intellectual properties. It provides an insight into the monopoly rights conferred to an inventor for the development of innovative processes and products. The course also includes legal perspectives of biotechnological inventions preferably products and processes of genetic modification.

COURSE OBJECTIVES: The course imparts in depth knowledge about intellectual property rights, its types, differences and uses. The students will be exposed to patent drafting, analyzing and comparing with case studies. The course provides essential information to students about the exploration of IP into the field of biotechnology sector with relevant case studies.

Date :10th June ,2022.

Time: 12:00p.m to 1: 00p.m

Venue: BT classroom 3

Speaker:Dr. Sarasija Padmanabhan,Patent Consultant ,Indian Institute of Science Campus ,India.

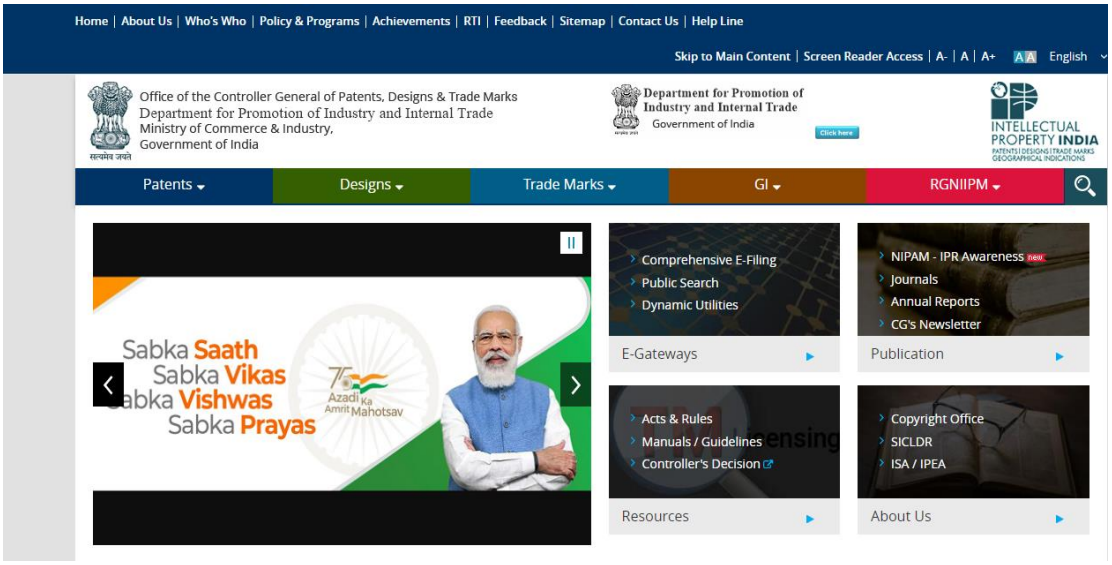
Session 4: **Patent Filing and its Ratification**

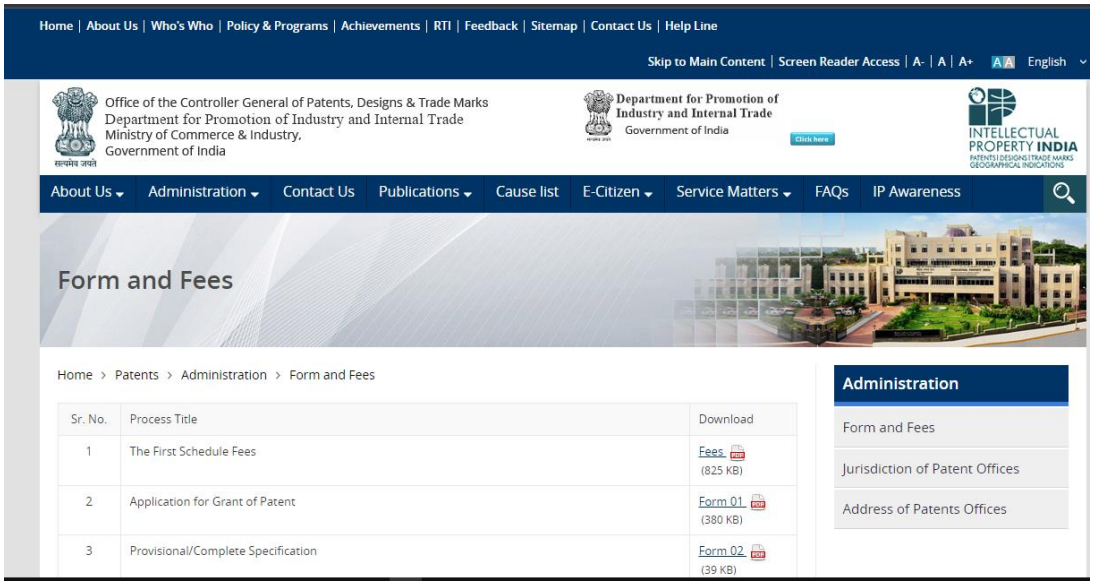
The session started by introducing the students to various stages from patent filing to granting of the patent. The stages comprised of filing of application (proven/complete), filing patent in the country of origin. Publications of applications, Request for Examination, Examination issue of FER and Granting of Patents. The speaker then enlightened the students on the Patent Act 1970 that came into action in the year 1972, which forms the principal law for patenting system in India. The various forms with respect to the filing and the website link were shared with students. The details are as follows.

Patent Amendment

Reduction in patent fee cost, not for an individual but for a group up to about 80% as of 2022.

Website : https://ipindia.gov.in/





The speaker mentioned that the forms and fees also contains request of examination. The application filed is examined against prior art. Where One invention is considered per application: Application fee for up to one priority, up to 30 pages and 10 claims to be included. For every page above 30 there is a cost associated with it .18 months after first filing the patent is published. The speaker then ended the session by explaining the issues of FER, regulations with respect to pre-grant and regulation fees.

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IPR(Intellectual Property Rights) Report--Session 5

DEPARTMENT OF BIOTECHNOLOGY

Course Title	**INTELLECTUAL PROPERTY RIGHTS**										**Credits**	**0**			
Course Code	**1**	**9**	**B**	**T**	**6**	**N**	**C**	**I**	**P**	**R**	**L-T-P-S**	**0**	**0**	**0**	**0**

COURSE PRE-REQUISITES: Microbiology, Basics of biomolecules, Biochemistry, Genetic engineering, Bio analytical techniques,

COURSE DESCRIPTION: IPR syllabus in the curriculum emphasize on the legal aspects of intellectual properties. It provides an insight into the monopoly rights conferred to an inventor for the development of innovative processes and products. The course also includes legal perspectives of biotechnological inventions preferably products and processes of genetic modification.

COURSE OBJECTIVES: The course imparts in depth knowledge about intellectual property rights, its types, differences and uses. The students will be exposed to patent drafting, analyzing and comparing with case studies. The course provides essential information to students about the exploration of IP into the field of biotechnology sector with relevant case studies.

Date :13th June ,2022.

Time: 12:00p.m to 1:00p.m

Venue: BT classroom 3

Speaker:Dr. Sarasija Padmanabhan,Patent Consultant ,Indian Institute of Science Campus ,India.

Session 5: **Patent strategy**

The speaker started the session by describing how strategy is taken to protect one's creation. To overcome prior art one has to overcome all claims of prior art and give an outcome. There are two kinds; Offensive strategy: To claim using a single claim and Defensive strategy- to Claim is done in many sequential claims. She then moved on by giving examples for better understanding on patent strategy. The example stated- If our interest lies in Vietnam our first filing must be done in India as it is the country of origin then in Vietnam. In this case someone from Burma can use it but it is not patentable again. A Fee can be paid to maintain the patent but if the patent does not have enough return, then it can be stopped. Additionally, an Invention has 2 parts, the claimed part and the unclaimed part. The unclaimed part is the left part and a missed opportunity to claim and hence it is not protected by the patent office. If the part of the claim lies in prior art, then there is an objection from the patent office. The speaker then enlightened on prior art, where she explained how prior aer is subjective, anything available to the examiner is prior art. E.g There can be two compounds to prevent cancer, one has OH and the other OCH_2 as functional groups. The second one demonstrated a better efficacy but the first is prior art. There was an argument that the second compound improved lipophilicity which was not done

in the prior art. The speaker mentioned that there is always a designing with respect to prior art. The session was then ended by concluding on how patents can be granted with respect to the strategy designed. All the students were very happy with the session.

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IPR(Intellectual Property Rights) Report--Session 6

DEPARTMENT OF BIOTECHNOLOGY

Course Title	**INTELLECTUAL PROPERTY RIGHTS**										**Credits**	**0**			
Course Code	**1**	**9**	**B**	**T**	**6**	**N**	**C**	**I**	**P**	**R**	**L-T-P-S**	**0**	**0**	**0**	**0**

COURSE PRE-REQUISITES: Microbiology, Basics of biomolecules, Biochemistry, Genetic engineering, Bio analytical techniques,

COURSE DESCRIPTION: IPR syllabus in the curriculum emphasize on the legal aspects of intellectual properties. It provides an insight into the monopoly rights conferred to an inventor for the development of innovative processes and products. The course also includes legal perspectives of biotechnological inventions preferably products and processes of genetic modification.

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Date :17th June ,2022.

Time: 12:00p.m to 1:00p.m

Venue: BT classroom 3

Speaker: Dr. Sarasija Padmanabhan,Patent Consultant ,Indian Institute of Science Campus ,India.

Session 6: **Patent strategies(Continued)**

The speaker started the session by elaborating more on the 2 types of strategy. Examples were given for both types. The speaker moved further into the session by describing on Patent Family on how patent enters various jurisdictions. For ex; if there are 9 technologies, then all will enter different jurisdictions. There was a discussion regarding elimination of waste, peruse unicorn patent protection. The session became even more interesting when students presented their case studies assigned to them. Students were divided into groups of 5 to 7 members. The first group presented a case on Illumina vs MGI. The summary of the discussion included following points and all the students actively participated in the group session.

- Five Illumina patents were in issues (the '578', '289', '433', '412' and '415' patents).
- Three of the patents, concerning modified nucleotides, were considered together.
- In light of challenges on the basis of obviousness, priority, insufficiency and added matter, amendments were permitted to each of these patents and each was held to be valid as amended.
- Claims of each of the three patents had been infringed('578', '289' and '433'patents).
- The fourth patent, for an improved method of nucleotide detection, was invalid for obviousness over the cited prior art and was found not to be infringed('412'patent found to be invalid for lack of inventive step).
- The fifth patent, entitled "Dye compounds and the use of their labelled conjugates", was valid as amended and infringed('415' patent).

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IPR(Intellectual Property Rights) Report--Session 7

DEPARTMENT OF BIOTECHNOLOGY

Course Title	INTELLECTUAL PROPERTY RIGHTS										Credits	0			
Course Code	1	9	B	T	6	N	C	I	P	R	L-T-P-S	0	0	0	0

COURSE PRE-REQUISITES: Microbiology, Basics of biomolecules, Biochemistry, Genetic engineering, Bio analytical techniques,

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Date :20th June ,2022.

Time:12:00p.m to 1:00p.m

Venue: BT classroom 3

Speaker :Dr. Sarasija Padmanabhan,Patent Consultant ,Indian Institute of Science Campus ,India.

The session started with continuation of group presentation from next 2 groups. Students were divided into group of 2 consisting of 5 members each and they were asked to choose case studies based on respective case laws. Students presented their case with lot of energy and enthusiasm. The following points were discussed during the session and the speaker provided her inputs for better understanding of the patent laws.

Group 2 presented a case on **"**England and Wales Court of Appeal (Civil Division) Decisions"

Summary of the discussion:

WYETH LLC was Appellant and MERCK SHARP & DOHME LIMITED were the Respondants in this case.European Patent (UK) No. 2 676 679 entitled "Formulations which stabilize and inhibit immunogenic compositions" whose Proprietor is Wyeth with a priority date - 26 April 2006. At trial Wyeth accepted that, 13V vaccine of de le pena can be progressed by adding siliconized container means, buffer, & aluminium salt.10v and 11v from, Sanofi and GSK were both abandoned, but obviousness from de le pena.De la Pena was a spanish paper by three workers from Wyeth Farma SA in Madrid.The judge found at [337] that the difficulties encountered by sanofi and GSK were specific to those companies and not innate to the task. The evidence of Prof Eskola, Wyeth's expert

vaccinologist, in his second report made a number of points about de la pena. The judge referred at [338] to the existence of materials which showed that Wyeth was infact carrying out clinical trials on 13v up to priority date, but that these were only relied on MSD to rebut any suggestion that Wyeth's 13v project had been dropped.

Group 3 presented the case **"**SANDOZ LIMITED and TEVA PHARMACEUTICAL INDUSTRIES LIMITED against BRISTOL-MEYERS SQUIBB HOLDINGS IRELAND UNLIMITED COMPANY and PFIZER INC.(BMS)"

Summary of the discussion:

This is a case study related to the claims made by two companies namely **SANDOZ LIMITED** and **TEVA PHARMACEUTICAL INDUSTRIES LIMITED** against **BRISTOL-MEYERS SQUIBB HOLDINGS IRELAND UNLIMITED COMPANY** and **PFIZER INC.(BMS).** The judge for this case was MR. JUSTICE MELLOR. The patent filed by BMS was related to drug APIXABAN. That first action was brought by SANDOZ against BMS which commenced on 15th December 2020. The second action was brought by TEVA against BMS on 16th February 2021.

Both these actions ('the Formulation Actions') originally sought revocation of five Formulation Patents held by BMS, namely **EP (UK) 2 538 925, EP (UK) 3 017 811, EP (UK) 3 246 021, EP (UK) 3 251 660, and EP (UK) 3 257 500.**

Although on 16th April 2021 Sandoz reached a Settlement Agreement with BMS as a result it claimed for revocation of only 1 patent i.e EP 021, while TEVA doesn't make any agreement. The Court does not have sufficient information or a sufficient understanding of the issues to be confident enough to impose a limitation on the number of independent valid claims that the patentee can assert. In other cases, the Court will be able to develop a sufficient understanding. The number of independently valid claims does tend to decrease so that at trial, even if Ms. Edwards-Stuart identifies 15 claims alleged to be independently valid in the course of this action, much doubt that there will be 15 independently valid claims in issue at trial. 9 claims in the five patents which Teva are seeking to invalidate. The particular circumstances of this action and these five patents, Teva's application in part was agreed.

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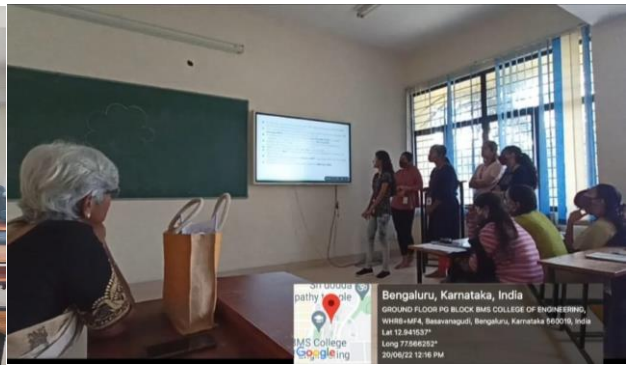

IPR(Intellectual Property Rights) Report-session 8

DEPARTMENT OF BIOTECHNOLOGY

Course Title	**INTELLECTUAL PROPERTY RIGHTS**										**Credits**	**0**			
Course Code	**1**	**9**	**B**	**T**	**6**	**N**	**C**	**I**	**P**	**R**	**L-T-P-S**	**0**	**0**	**0**	**0**

COURSE PRE-REQUISITES: Microbiology, Basics of biomolecules, Biochemistry, Genetic engineering, Bio analytical techniques,

COURSE DESCRIPTION: IPR syllabus in the curriculum emphasize on the legal aspects of intellectual properties. It provides an insight into the monopoly rights conferred to an inventor for the development of innovative processes and products. The course also includes legal perspectives of biotechnological inventions preferably products and processes of genetic modification.

COURSE OBJECTIVES: The course imparts in depth knowledge about intellectual property rights, its types, differences and uses. The students will be exposed to patent drafting, analyzing and comparing with case studies. The course provides essential information to students about the exploration of IP into the field of biotechnology sector with relevant case studies.

Date :24 th June ,2022.

Time:12:00p.m to 1:00p.m

Venue: BT classroom 3

Speaker :Dr. Sarasija Padmanabhan,Patent Consultant ,Indian Institute of Science Campus ,India.

Sesssion 8: Types of claims

The session started with explanation on prior art and the ways to overcome it. For example, if use of coal and liquid gas is considered as an invention - Find out what is the difference in invention. The speaker mentioned that the claims can be of 2 types. Independent claim where the Patent application

may have more than 1 independent claim and Depended claim- fall all back during examination. The speaker elaborated further on the differentiation of both claims and moved on to parts of claim. There are 3 parts in every claim

1. Preamble - describes area of technology of the claim.It is a short introductory statement.
2. Transition-connecting the preamble to the body .
3. A body

Eg : A wagon (preamble) comprising (transition)

She then depicted the punctuations to be considered for claims; - A comma separates the Preamble from Transition. - A colon Transition from Body. The small paragraphs that define and describe the logical elements are separated by a semi-colon. The speaker emphasized on the various errors that could be done while drafting a claim. Few of the samples were given for better understanding of the concept.

1. No trademark in a claim.
2. Only to connect all elements of the claim we can use functional language.
3. Too specific clams or narrow may not be valuable.
4. Too General or Broad may not be patentable.

The session was very interesting for the all the students and they gave a positive feedback.

Gallery:

IPR(Intellectual Property Rights) Report-Session 9

DEPARTMENT OF BIOTECHNOLOGY

Course Title	INTELLECTUAL PROPERTY RIGHTS										Credits	0			
Course Code	1	9	B	T	6	N	C	I	P	R	L-T-P-S	0	0	0	0

COURSE PRE-REQUISITES: Microbiology, Basics of biomolecules, Biochemistry, Genetic engineering, Bio analytical techniques,

COURSE DESCRIPTION: IPR syllabus in the curriculum emphasize on the legal aspects of intellectual properties. It provides an insight into the monopoly rights conferred to an inventor for the development of innovative processes and products. The course also includes legal perspectives of biotechnological inventions preferably products and processes of genetic modification.

COURSE OBJECTIVES: The course imparts in depth knowledge about intellectual property rights, its types, differences and uses. The students will be exposed to patent drafting, analyzing and comparing with case studies. The course provides essential information to students about the exploration of IP into the field of biotechnology sector with relevant case studies.

Date :27 th June ,2022.

Time:12:00p.m to 1:00p.m

Venue: BT classroom 1

Speaker :Dr. Sarasija Padmanabhan,Patent Consultant ,Indian Institute of Science Campus ,India.

The session started with continuation of group presentation from next 2 groups. Students were divided into group of 2 consisting of 6 to 7 members each and they were asked to choose case studies based on respective case laws. Students presented their case with lot of energy and enthusiasm. The following points were discussed during the session and the speaker provided her inputs for better understanding of the patent laws.

Group 4 presented case study on " INSULET CORPORATION (Claimant) Vs ROCHE DIABETES CARE LIMITED (Defendant)"

Summary:

Patent was a "Device and system for patient infusion" and states that it relates particularly to "small, low cost, portable infusion devices that are useable to achieve precise, sophisticated,

and programmable flow patterns for the delivery of therapeutic liquids to a mammalian patient".Insulet claimed that Roche has infringed the Patent: both directly and indirectly directly, by the manufacture and sale of kits containing the Solo pump and related components; indirectly, by supplying of consumable components called – "Solo Consumables".Roche denies infringement and counterclaims for revocation of the Patent, by using two prior art documents known as "PhiScience" and "MiniMed".The trial was conducted fully remotely. There was a skilled team set up where both the parties cited the approaches to the issue the team will be governing the approach and give the solutions for the obvious problems. The Patent is entitled "Device and system for patient infusion" and explains, "The present invention relates to small, low cost, portable infusion devices that are useable to achieve precise, sophisticated, and programmable flow patterns for the delivery of therapeutic liquids to a mammalian patient. "The Patent starts with a discussion of parenteral drug delivery. It describes existing ambulatory infusion pumps and their benefits, noting that they "allow control or programming via electromechanical buttons or switches located on the housing of the device". The Patent acknowledges prior art including PhiScience and Minimed. The Patent concludes its description of the prior art as follows: "None of the above disclose a programmable and adjustable infusion system that is precise and reliable and can offer clinicians and patients a small, low cost, light weight, simple to use alternative for parenteral delivery of liquid medicines". The inventor's purpose, Roche submits, is not merely to achieve the benefits which are the overall purpose of the Patent, but also to explain that this will be achieved by the means which are specifically identified in Integer 1G: i.e. removing user interfaces so that there is a 'lack of' such components (such as electromechanical switches or other user interfaces) on the device, or so that the 'housing is free of' those components.Insulet's submissions went to safety aspects of the device and rested on the fact that the Patent permits a housing which is otherwise free of user interfaces to incorporate an emergency stop button as a safety mechanism.

Group 5 presented a **Case on "Regeneron Pharmaceuticals Inc (Respondent) v Kymab Ltd (Appellant)"**

Summary :

In 2001, Regeneron filed two patents (EP(UK) 1 360 287 and EP(UK) 2 264 163) to protect an invention relating to genetically-modified mice.Regeneron alleged infringement by Kymab Ltd of claim 1 in the 163 Patent and claims 5 and 6 of the 287 Patent by the offer to the pharmaceutical industry of its own "Kymouse", a transgenic mouse with a Reverse

Chimeric Locus .The judge found infringement proved, but that all three claims were invalid for insufficiency.This is a product claim, seeking a monopoly for the “making” of a genetically engineered mouse having the characteristics described in the claim. Regeneron’s patents did not enable a skilled person to make mice containing more than a very small section of the human variable region.Regeneron was claiming a monopoly which was far wider than its contribution. *(Range of claim)*.Kymab argued that the Regeneron’s patent were too broad and did not contain enough information, when combined with the general knowledge already available to the public, for a skilled person or team to make the full range of genetic modifications claimed on the patent.A transgenic mouse was created by Regeneron using a method that was newly invented by them. The method was applicable to only a small part of the range claimed by them.Kymab created a method that was able to get the same result for the entire range that was claimed by Regeneron.

Regeneron sued Kymab for infringement of their claim. Since a new method was invented by Regeneron, the initial verdicts favoured them. Kymab pointed out that the method invented by Regeneron did not satisfy the entire range claimed by them. A skilled person was not able to obtain the results given, for a large part of the range, using the teaching in the patent and general knowledge and hence the patent should be invalid on the basis of insufficiency. The claim was finally declared invalid due to insufficiency.

IPR(Intellectual Property Rights) Report-10

DEPARTMENT OF BIOTECHNOLOGY

Course Title	INTELLECTUAL PROPERTY RIGHTS										Credits	0			
Course Code	1	9	B	T	6	N	C	I	P	R	L-T-P-S	0	0	0	0

COURSE PRE-REQUISITES: Microbiology, Basics of biomolecules, Biochemistry, Genetic engineering, Bio analytical techniques,

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Date :1st July ,2022.

Time:12:00p.m to 1:00p.m

Venue: BT classroom 3

Speaker :Dr. Sarasija Padmanabhan,Patent Consultant ,Indian Institute of Science Campus ,India.

The session continued with Presentation by Group 6 on case study entitled "**E**ngland and wales high court (patent court) decisions**"** The summary of the case study is given as follows.

Team Members:

1. **Ram Manas N**
2. **Shahedha Noor**
3. **Bhargavi K**
4. **C. Pooja**
5. **Namratha V**
6. **Sriniketh**
7. **Anupriya Mitra**

Summary :

Claimants: Andrew Waugh QC, referred as "Alcon".

Defendants: Anna Edwards-Stuart, and Justin Turner QC and Daniel Selmi.

One of the issues that fell away during trial was an allegation that the Patent was obvious over another prior art called “Karlsson”

“Karlsson”(Abstract No. 55 entitled “Receptor profile of PhXA41, a new phenyl substituted prostaglandin ester” by Maritha Karlsson et al. published in Experimental Eye Research Vol 55, Supplement 1 in or around September 1992)

Karlsson was referred to in Stjernschantz (the other patent) and the attack over it was closely related to that over Stjernschantz. It was a pragmatic decision by the Defendants to drop it in the way of the evidence; it was reasonable to run it up until then.

The patent :

[0001] The present invention relates to the treatment of glaucoma and ocular hypertension. In particular, the present invention relates to the use of fluprostenol isopropyl ester to treat glaucoma and ocular hypertension wherein the dosage range for topical administration of fluprostenol isopropyl ester is between 0.05 and 10 micrograms per eye.

After then introducing the structures of PGF2a, cloprostenol and fluprostenol at [0002] and [0003], it describes the problem of the side effects from naturally occurring prostaglandins when used to lower IOP, and earlier attempts to address them.

[0004]:Naturally-occurring prostaglandins are known to lower intraocular pressure (IOP) aftertopical ocular instillation, but generally cause inflammation, as well as surface irritation characterized by conjunctival hyperemia and edema.

[0010] It has now been unexpectedly found that fluprostenol isopropyl ester wherein the dosage range for topical administration of fluprostenol isopropyl ester is between 0.05 and 10 micrograms per eye shows significantly greater IOP reduction than the compounds of Stjernschantz et al., while having a similar or lower side effect profile. In particular, it appears that the addition of a trifluoromethyl group to the meta position on the phenoxy ring at the end of the omega chain provides a compound having excellent IOP reduction without the significant side effects found with other, closely related compounds.

[0011] In addition, it has also been unexpectedly found that fluprostenol isopropyl ester wherein the dosage range for topical administration of fluprostenol isopropyl ester is between 0.05 and 10 micrograms per eye is useful in treating glaucoma and ocular hypertension. In particular, topical application of ophthalmic compositions comprising this novel fluprostenol analogue results in significant IOP reduction.

Claim 1 of the Patent as upheld by the TBA is in the EPC 2000 form for second medical use claims A topical ophthalmic composition for use in the treatment of glaucoma and ocular hypertension comprising a therapeutically effective amount of fluprostenol isopropyl ester wherein the dosage range for topical administration of fluprostenol isopropyl ester(FIE) is between 0.05 and 10 mg per eye.

Claim 2 is a Swiss claim. Neither side says there is any difference from claim 1 for the purposes of these proceedings.

It is convenient at this point to address Alcon’s contentions as to the technical contribution of the Patent:i) A new and useful therapy for the treatment of glaucoma (this is on the assumption that the anticipation attack failed)

ii) A prostaglandin analogue which lowers IOP but without the hyperemia associated with PGF2a.

iii) A prostaglandin analogue which is better than latanoprost in terms of IOP lowering but with comparable good/acceptable hyperemic properties

iv) A prostaglandin analogue with less hyperemia than the structurally closest analogue from the Stjernschantz 417 patent application identified in the Patent, But there is no relevance in last two 2 points.

After considering the factual basis of ii) and iii) above in reviewing the teaching of the Patent's specification, and have accepted them. Point i) is also true, but it is important that it be taken with points ii) and iii) as a whole, because in total they mean that the technical contribution is a better glaucoma treatment (than latanoprost or PGF2a) and not merely an alternative one.

It was submitted for the Defendants that PGF2a (itself or as the isopropyl ester) was suitable "for use" in treating glaucoma. Counsel for the Defendants accepted that the side effects of PGF2a were recognised to be undesirable, and that improving side effects was part of the relevant motivation of the skilled person.

Issue of claim interpretation does not matter. In this case it was misunderstood.Counsel for the Defendants accepted that there must come a point where side effects are so bad that a drug is not suitable for use despite having an effect on the disease state in question. In particular,they accepted that lethal side effects would prevent a drug being suitable for use. boundary must depend on context, the disease state including its severity, and the nature and effect of the side effects.

In the current context, glaucoma was regarded as an incurable, long-term condition. Neither ocular irritation nor hyperemia would be considered unbearable in the short term, but in the longer term they would be regarded as very burdensome, and were recognised as having a very material adverse effect on patient compliance. They were not just inconveniences ,therefore consider that PGF2a was not suitable for use in treating glaucoma. Taking all these matters together the judge rejected the obviousness attack over Stjernschantz. Hehad done so on the basis of the Defendants' view of the skilled team. The Defendant's' case would only have been more difficult on Alcon's view of the skilled team.

The pleaded point was as follows:

" In the event that the claims of the Patent are not obvious because it was understood that the administration of PGF2 isopropyl ester would cause ocular inflammation and irritation, the Patent fails to make plausible that the compounds of the invention are suitable for use in treating glaucoma and ocular hypertension. In particular, the data in the specification of the Patent fails to evidence an improvement in these side effects when the compounds of the invention are used over PGF2 isopropyl ester."

"Inflammation" was changed to "hyperemia" by an amendment made during trial when it was pointedout by Alcon that the two are not necessarily synonymous. But both sides had been proceeding intheir expert evidence on the basis that the squeeze was alleged to operate in relation to hyperemia,so he allowed the amendment, over Alcon's objection

The point fails on the fact that the Patent does make itplausible that FIE causes reduced hyperemia compared to PGF2. The pleading does not allege that the Patent does not make plausible a better effect on IOP lowering. Overall therefore the squeeze made no difference and does not help the Defendants.

The conclusions are:i) The allegation of anticipation by EP 800 fails. ii) The allegation of obviousness over Stjernschantz fails. iii) The Patent is valid. iv) There is no need for any amendment.

Pictures :

IPR(Intellectual Property Rights) Report 11

DEPARTMENT OF BIOTECHNOLOGY

Course Title	INTELLECTUAL PROPERTY RIGHTS										Credits	0			
Course Code	1	9	B	T	6	N	C	I	P	R	L-T-P-S	0	0	0	0

COURSE PRE-REQUISITES: Microbiology, Basics of biomolecules, Biochemistry, Genetic engineering, Bio analytical techniques,

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Date :4 th July ,2022.

Time:12:00p.m to 1:00p.m

Venue: BT classroom 3

Speaker :Dr. Sarasija Padmanabhan,Patent Consultant ,Indian Institute of Science Campus ,India.

Presentation by Group 7

Topic : Case Study COLOPLAST (CLAIMANT) V/S SALTS HEALTHCARE LIMITED (DEFENDANT)

Team Members :

1. **ANOKSHA BHATTACHARJEE**
2. **SAHANA J**
3. **JOTHIKA K**
4. **AYUSH L**
5. **SHIVARAJA B**
6. **SRIRAKSHA A NADIG**
7. **ASHRITA NIHARIKA ASHWIN**

The summary:

In this action the Claimant, Coloplast A/S ("Coloplast") claims that its patent has been infringed by the Defendant, Salts Healthcare Limited ("Salts"). Salts denies infringement and counterclaims for revocation of the Patent on the bases of a lack of novelty, lack of inventive step, insufficiency, AgrEvo obviousness and added matter.

In around November 2017 Salts launched its "Confidence BE" range of ostomy bags.The Patent was filed on 17 May 2013. In Coloplast's original Particulars of Infringement dated 5 April 2019. There were six witness of fact for Salts whose evidence was unchallenged and therefore be accepted. It is necessary to comment on the expert witnesses each of whom was cross examined.

The Patent was directed at a notional person (or team of persons) with a practical interest in its subject matter, namely bags for collecting human waste.

There was a dispute between the parties as to the extent to which the skilled person may have worked with or be familiar with feminine care and adult incontinence products and diapers.

The patent titled as "Comfort layer for a collecting bag" but, as its claims make clear, it is limited to ostomy bags. An ostomy (or stoma) is an opening in a human body created surgically to allow the discharge of body waste. An ostomy bag connects to the stoma to receive such waste. It includes a pouch made of a layer of impermeable material (the barrier film) with a flange which allows the bag to be connected to the stoma. The Patent concerns a further layer which can be added to such a bag and which is known as a comfort layer. As its name suggests, a comfort layer is intended to make wearing an ostomy bag more comfortable.

While Salts' arguments that the Patent was invalid due to novelty, insufficiency, or additional substance were rejected, Salts' argument that the Patent was invalid due to obviousness—that is, that the notion relied on by Coloplast under the Patent was not an inventive concept—was accepted.

Presentation by Group 8

Topic : Case Study Latvia MGI Tech SIA & Ors (defendants/appellants) –vIllumina Cambridge Ltd (claimant/respondent)

Team Members :

1. **Evangeline Lydia C**
2. **Vidhi D Jain**

The summary:

This case is a patent action about DNA sequencing technology

Claimants; Solexa, bought by Illumina Defendants: MGI, companies in the beijing Genomics Institute group
MGI seeks to sell all DNA Sequencing systems in UK, Illumina claims to that these systems infringe various of its patents

3 patents: EP 578, EP 289, EP 433 , relate to an azidomethyl group as a reversible chain terminator in sequencing by synthesis.

MGI pleaded that the modified nucleotide patents are obvious over four pieces of prior art:

i) International patent application filed by SRI International and published on 16th May 1991.
ii) International patent application filed by a group at Columbia University and published on 11th April 2002.
iii) A paper entitled “1-Alkythioalkylation of Nucleoside Hydroxyl Functions and Its Synthetic Applications: A New Versatile Method in Nucleoside Chemistry”, Zavgorodny et al., Tetrahedron Letters (1991)
iv) A paper entitled “S,X-acetals in nucleoside chemistry. III1. Synthesis of 2’- and 3’-O-azidomethyl derivatives of ribonucleosides”, Zavgordony et al., Nucleosides, Nucleotides and Nucleic Acids (2000)
.

The fluorescence issues - the 412 and 415 patents:

It is related to the patents EP 412 (MGI opposes infringement made by Illumina) and EP 415(invalidity).

MGI proposes collocation argument based on 2 documents: fluorescent dyes and linkers

Due to the pandemic, a hybrid trial was conducted where the core legal teams were seated in the physical courtroom and the rest, working remotely.

MGI contended that based on the disclosure of the patents, the problem the patentee was trying to solve was the identification of removeable protecting groups which could meet the requirements for use in methods of sequencing by synthesis; in other words, to find improved removable protecting groups to act as reversible chain terminators in sequencing by synthesis.
Illumina’s identification of a successful reversible blocking group for the 3' position for use in sequencing by synthesis. At this stage nothing turns on the differences between these formulations, nor does it follow that the skilled person, however defined, has that problem in mind. People with a particular interest in improving Sanger sequencing were not focussed on trying to find new techniques, they were trying to optimise the known and very successful method.
sequencing by synthesis was an established field of research by 2002.
Therefore the person skilled in the art at the 2002 priority date, at least for the purposes of considering obviousness, is a team working on research into sequencing by synthesis.

6TH SEM
STUDENTS
ARE
BEST
Introduction
GPS Map Camera
napathy temple
BMS College
of Engineering
Google
Bengaluru, Karnataka, India
First floor ,New, BMS COLLEGE OF ENGINEERING, Basavanagudi,
Bengaluru, Karnataka 560019, India
Lat 12.941209°
Long 77.565962°
04/07/22 12:25 PM

IPR(Intellectual Property Rights) Report-12

DEPARTMENT OF BIOTECHNOLOGY

Course Title	INTELLECTUAL PROPERTY RIGHTS										Credits	0			
Course Code	1	9	B	T	6	N	C	I	P	R	L-T-P-S	0	0	0	0

COURSE PRE-REQUISITES: Microbiology, Basics of biomolecules, Biochemistry, Genetic engineering, Bio analytical techniques,

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Date :11th July ,2022.

Time:12:00p.m to 1:00p.m

Venue: BT classroom 3

Speaker :Dr. Sarasija Padmanabhan,Patent Consultant ,Indian Institute of Science Campus ,India.

Plant Variety Protection Act

- Developed International Treaty of Plant Genetic Resources .
- Monsanto's terminator Technology which produced BT variety seeds that cannot be used .
- Gene fund :Genes for particular Plants .

CVD –Concention For Biodiversity .

TRIPS(Trade Related International Property Rights)

- There is a Journal ,anything new coming in must be entered .
- Compulsory Licencing –when there is a new variety /plant selling at a high cost and alternatively if farmer produces at a very low cost then licencing can be granted made compulsory .

What is a new variety ?

Novel if the propagating or harvested material of the variety not sold or otherwise exploited.

The time period being :

- 1 year in India .
- More than 6 years outside of India

How to register for plant variety protection act ?

- Novelty
- Distinctiveness
- Uniformity
- Stability (same even after propagation)

Notification and file an application ,examination ,conduction of the DUS test ,Examination of the test results and Certification .

Breeder's Rights

- An exclusive right on the breeder or his successor, his agent or licensee, to produce, sell, market, distribute, import or export the variety. A breeder may authorize any person to produce, sell, market or otherwise deal with the variety registered under this Act. Breeder shall enjoy provisional protection of his variety against any abusive act committed by any third party during the period between filling of application for registration and decision taken by Authority.

Researcher's Rights

- The use of any variety registered under this Act by any person using such variety for conducting experiment or research The use of a variety as an initial source of variety for the purpose of creating of other varieties: • Provided that the authorization of the breeder of a registered variety is required where the repeated use of such variety as a parental line is necessary for commercial production of such other newly developed variety.

Farmer as a Breeder

A farmer who has bred or developed a new variety shall be entitled for registration in the like manner as a breeder of a variety under the Act.

Pictures :