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Entrepreneurs are the harbingers of prosperous society. An entrepreneur not only creates employment but also contributes to the economic development of the country. With the growth of scientific temperament in society people who have created enterprises based on scientific discoveries have grown in large numbers. One such field of entrepreneurship is based on biotechnology. This chapter highlights the role and relevance of entrepreneurs in general and biotech entrepreneurs in particular. The chapter also has exhibits of cases from the real world about entrepreneurs who have carved a niche for themselves by successfully launching biotechnology-based enterprises. Besides, the chapter also discusses the contemporary legislations governing biotechnology-based enterprises.

### 13.1 CONCEPT OF ENTREPRENEURSHIP

The root word for the term ‘entrepreneur’ is the French word ‘entreprendre’ that means ‘to undertake’. Entrepreneur thus, is an individual who undertakes an activity foreseeing business opportunity. An entrepreneur organises resources needed for starting the enterprise and also bears the risk involved in the process. Thus, there

- 13.1 *Concept of Entrepreneurship*
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are three prominent roles that an entrepreneur fulfils—an innovator, organiser and a risk bearer.

While performing the three roles mentioned above, an entrepreneur does significant tasks for self and the society. As an innovator, an entrepreneur is the person who brings out new products into the market. As an organiser, he/she organises the factors of production in order to take advantage of opportunity in the market. Finally, as a risk bearer he/she shoulders all uncertainties associated with the venture.

### Box 1

1. Howard Stevenson (1983) defined that “Entrepreneurship is the process by which individuals pursue opportunities without regard to the resources they currently control.”
2. “Entrepreneurship is the persistent progression towards an innovative solution to a key problem. It’s the **constant hunger for making things better** and the idea that you are never satisfied with how things are.” – *Debbie Roxarzade, founder and CEO of Rachel’s Kitchen*
3. “At its core, [entrepreneurship] is a mindset – a way of thinking and acting. It is about **imagining new ways to solve problems and create value**. Fundamentally, entrepreneurship is about...the ability to recognise [and] methodically analyse [an] opportunity, and ultimately, to capture [its] value.” – *Bruce Bachenheimer, Clinical Professor of Management and Executive Director of the Entrepreneurship Lab at Pace University*
4. “To be a successful entrepreneur you must have a **passion for learning** – from customers, employees and even competitors.” – *James Bedal, CEO of Bare Metal Standard*

### 13.1.1 Importance of entrepreneurship

Entrepreneurship is widely regarded as the best way to augment the growth of an economy. Entrepreneurs have played a significant role in developing some of the best economies of the world like that of USA and Japan. In India too we have had several communities who have played a significant role of entrepreneurs for the economic development of our nation. Entrepreneurs are the prime movers of innovation and the introducers of new products into the market. Therefore, they play a key role in improving

the lives of our societies. Enumerating the importance of entrepreneurship, we see that they:

- (a) help in capital creation by bringing together the resources of the people.
- (b) are employment creators and their role is pivotal. By creating employment opportunities, the standard of living of people increases and also the purchasing power of the people augments.
- (c) help in developing total community. If employment is diversified among small entrepreneurial units, it promotes overall standard of living leading to stability and higher quality of community life.

For people who are open to challenges and ready to take risks, entrepreneurship is the most appealing activity the success of which can be hugely rewarding. Entrepreneurs are an asset to any nation, they change the lifestyle of the people of a country by introducing new products and services. If we look at the Indian Information Technology (IT) revolution in the early 1990s, we see that the effect of this has led to phenomenal growth of the Indian economy in itself over the years. This IT revolution created many ancillary industries that became valuable creators of employment opportunities for the youth of our country. Today, the start-up revolution has taken the whole of India by storm. The Government promotion of entrepreneurial spirit through various schemes and tax benefits has made entrepreneurial efforts worth trying.

Entrepreneurship is regarded as the panacea for the unemployed in an economy. Self-employment empowers an individual and helps in bringing about the social change for community development.

### **13.1.2 Qualities of a successful entrepreneur**

India has had some of the finest entrepreneurs in history that laid the foundation of Indian economy. We can see that they all possess certain distinct qualities, some of which are summarised below:

- 1. Initiative:** Being an innovator is a significant characteristic of an entrepreneur. Entrepreneur takes initiative at the right time to launch a venture, enduring all the struggles of initiation of a new venture.

## Box 2

### Story of Dr Krishna Ella, founder of Bharat Biotech International Ltd.

As students we sometimes ask our teachers or ourselves “Why am I learning this? Will I even use it in real life?”. Well, if your life goals are similar to those of Dr. Krishna M. Ella, that is, to create massive positive changes through scientific innovation, then you just might.

Dr. Ella is the Chairman and Managing Director of Bharat Biotech International Limited (BBIL), which he co-founded with his wife in 1996 in Hyderabad, Telangana. A person hailing from a rural background and born in a village Nemili in Tamil Nadu, started his early education from the same village, had his share of ups and downs to achieve the feat what he is today. He completed his higher schooling and intermediate course in Life Sciences from Madras followed by completing his higher degrees in Agriculture from Maharashtra and later from Karnataka. In order to gain marketing experience, he worked with the Agricultural Division of a Pharmaceutical company in India as well.

He also pursued Masters in Science (specialisation in Plant Pathology) at the University of Hawaii and doctoral programme at the University of Wisconsin, Madison, after getting a scholarship. Followed by his Ph. D. in 1993, Dr. Ella joined the Medical University of South Carolina, Charleston, where he made a shift from Plant Pathology to human and yeast molecular biology. While conducting regular research, he started thinking of innovative ideas for the development and production of Recombinant Hepatitis B Vaccine.

In 1996, Dr. Ella returned to India and with the encouragement of his wife and his mother, set up a small laboratory in the city of Hyderabad. Their prime objective was to innovate in the development of affordable vaccines and biotherapeutics. As they wanted India to be known as the country that innovated and the name ‘Bharat Biotech International Ltd.’, was chosen. BBIL was established in 1997 in Hyderabad with the funds and assistance from angel investors. Since its inception, BBIL has produced over 4 billion doses of various human vaccines for diseases such as Hepatitis B, Rabies, Diphtheria, Rotavirus, and corona virus, etc., most of them for the Universal Immunisation Programme of India and for more than 120 developing countries to safeguard global public health.

COVAXIN® is Bharat Biotech’s 17th Vaccine and the first COVID-19 Vaccine which made in India. Dr. Ella and his team developed COVAXIN®, the inactivated whole virus and adjuvanted vaccine, in a record time of just eight months. COVAXIN® has been in use as a life saving vaccine against the COVID-19 pandemic since December 2020 across India and many other developing countries. WHO has also approved COVAXIN for emergency use against COVID-19.

Dr. Ella once said, “Solving today’s problem is not innovation, it is the ability to predict the future problem and finding solutions to solve an important problem, something that matters to public health.” He strongly believes in the potential of upcoming generation of students to shape the future of India. “For students of science, their focus on academic performance today can yield a better life for them and also for everyone around them. Many years from now, there will be a new generation of science students reading about a different entrepreneur in their textbook. You can be that entrepreneur too!”



**(Courtesy: Bharat Biotech International Limited (BBIL))**

- 2. Knowledge and skill:** An entrepreneur is a skilled individual who possesses the relevant knowledge relating to the industry, economy, consumer choices, technology, etc., and prospects of growth for the same in future.
- 3. Risk taker:** An entrepreneur is ready to take the uncertainties associated with the enterprise. An entrepreneur has the foresight to accept the long-term prospect of success for the enterprise. In doing so, he/she is ready to withstand the short-term risks associated with the venture.
- 4. Adaptability:** An entrepreneur is adaptable to the changing business environment. As an entrepreneur starts and grows the business, they constantly monitor the business environment and adapt themselves to the changes taking place in it.
- 5. Self-confidence:** An entrepreneur is confident of the decisions they are taking. This self-belief is a key factor that makes entrepreneurs successful and acts as a catalyst in making them take up risks.
- 6. Wealth creators:** Entrepreneurs are wealth creators that translate great ideas into commercial success. Those who succeed after taking these risks turn out to be wealth creators for themselves and for the nation they belong to, by providing valuable employment opportunities to the people. Thus, it is seen that every successful and economically developed nation has nurtured and promoted the entrepreneurial spirit among its people.

### 13.1.3 Difference between Entrepreneur and Intrapreneur

Entrepreneur and intrapreneur have similar values—that of innovation and creativity, the two are often used interchangeably. However, an entrepreneur and intrapreneur have distinctive differences. An entrepreneur is a person who takes risks to start a business venture in order to earn profit. They foresee the opportunities for products and services and coordinates with the factors of production to establish an enterprise. On the other hand, an intrapreneur is an employee of an organisation who promotes innovation among the employees of the organisation. They are hired to bring about success in a business venture.

### 13.1.4 Planning and Resourcing an Enterprise

#### **Business Planning—Preparation of a Feasibility Report**

While starting a new business venture, an entrepreneur is interested in knowing if it is feasible to start and run the enterprise. This is where a feasibility report needs to be prepared to evaluate the business idea and confirm the validity of the same. The steps in preparing the feasibility report are as under:

##### ***Step One: Conduct a Preliminary Analysis***

The first step in checking the feasibility of a business proposition is the screening of the project idea before investing extensive time, money and effort in the same. The entrepreneur describes as precisely as possible the product or service, the set of activities and the target market along with the way the new product or service is different from the existing one being offered in the market. If the analysis in the preliminary stage projects that there are chances of grave obstacles and unsurmountable hindrances, then it is advised not to proceed further with the venture idea. While, if the preliminary analysis shows positive outcomes, the entrepreneur conducts other stages of the feasibility analysis.

##### ***Step Two: Prepare a Projected Income Statement***

An Income Statement covering the direct and indirect costs is prepared. It should take into account the anticipated income growth curve. A backward computation of the projected income and the revenue necessary to generate that income can be derived to build a projected income statement.

##### ***Step Three: Conduct a market survey***

A good market survey is essential for a realistic projection of revenue. The major steps in a market survey are as follows:

1. Define the geographic influence on the market.
2. Analyse the environmental factors influencing a market.
3. Analyse the competitors in the market.
4. Determine the total volume in the market area and estimate the expected market share.
5. Estimate the market expansion opportunities.



**Step Four: Plan business organisation and operation**

In this stage, the operation and organisation structure of the business should be planned in detail to determine the technical feasibility and the costs associated with the start-up, the fixed investment and operation.

**Step Five: Prepare an Opening Day Balance Sheet**

The opening day balance sheet must reflect the assets and liabilities of the proposed venture as accurately as possible. The list must be a detailed account of source, cost and the method of financing the same. The liabilities incurred and investment required by the venture at the time of inception need to be clarified in detail.

**Step Six: Review and analyse the data**

This step is significant so that the business planner rechecks the steps performed so far. The projected Balance Sheet is re-examined and also evaluated for the risks and contingencies.

**Step Seven: Decision Stage**

This is the last stage in which the entrepreneur decides whether he/she should or should not proceed with the business idea. The entrepreneur decides to go ahead with the business idea only if the projections indicate growth potential and a minimum income. Anything that shows low growth prospect means that the business idea is not worth investing.

## 13.2 SOURCES OF FUNDS

**Define Start-up**

In entrepreneurial terminology, the term 'Start-up' has become a popular word. Under the Startup India Action Plan, startups that meet the definition as prescribed under G.S.R. notification 127 (E) dated 16 January, 2019 are eligible to apply for recognition under the programme. The startups have to provide support documents at the time of application.

*Eligibility criteria for startup recognition:*

- (a) The startup should be incorporated as a private limited company or registered as a partnership firm or a limited liability partnership.
- (b) Turnover should be less than INR 100 crores in any of the previous financial years.

- (c) An entity shall be considered as a startup up to 10 years from the date of its incorporation.
- (d) The startup should be working towards innovation or improvement of the existing products, services and processes and should have the potential to generate employment and create wealth. An entity formed by splitting up or reconstruction of an existing business shall not be considered a 'Startup'.

Assuming that a new enterprise would be a startup, here are seven sources of financing the new venture:

- 1. Personal investment:** The first investor in a business is the 'entrepreneur' himself/herself. By putting in his/her own money, the entrepreneur proves to bankers and other investors, his/her long-term commitment to the venture.
- 2. Venture capital:** Venture capitalists are investors that look for technology driven enterprises and companies that have a high growth potential. Some of the high growth potential sectors are Information Technology, Biotechnology, etc. The Venture Capitalists take an equity position in the company in order to help in developing a high-risk venture. They look for high return on investment when the business is developed, after which they may exit.
- 3. Angel investors:** Angel investors are generally, wealthy individuals who invest in promising startups. These investors are very often leaders in their own fields, who invest money, ideas and experience in the promising ventures. They tend to finance the early stages of business.
- 4. Business incubators:** Business incubators, also called accelerators, are investors who support high-tech sector by giving support to them in various stages of development. There are incubation centers in academic institutions and industrial cooperatives as well. Incubation phase lasts generally for two years only.
- 5. Government grant and subsidy:** Government agencies provide financing such as grants and subsidies in order to promote business.
- 6. Bank loans:** These are the most commonly used source of funding business ventures. For being eligible for a bank loan, a good idea itself is not enough, it should be complimented by an appealing business plan. Loans for start-ups typically require a personal guarantee from the entrepreneur.



## 13.3 ENTREPRENEURSHIP IN BIOTECHNOLOGY

### 13.3.1 Significance of Biotechnology Entrepreneur

Biotechnology entrepreneurship consists of all the activities that an entrepreneur does to build and sustain an enterprise based on biotechnological innovation. It is an enterprise built by the amalgamation of science and business.

Some definitions of Biotechnology Entrepreneurship given by experts are as under:

1. 'Biotechnology' by accepted definition, involves the use of living organisms or parts of living organisms through biological processing to develop new products or provide new methods of production—Damian Hine and John Kapeleris (2006)
2. The entrepreneur conceptualises, creates and commercialises a biotechnology product. Some of the life-saving medical products, advanced fuels and efficient crops have been researched, developed and commercialised through biotechnology enterprises.

The concept of bio-entrepreneurship was elaborated by A.D. Meyers (2008) as "Bio-entrepreneurship is the process of creating value from life science innovation. It is referred to by several names including—bioscience entrepreneurship, life science entrepreneurship or bioscience enterprise. Whatever the descriptor, the fundamental notion is about moving a life science discovery or invention from the research phase through development to a commercial market." Entrepreneurs are the harbingers of ideas that impact our lives. Human lifestyles have changed, developed and progressed due to the new products, services, ideas, events and technology introduced by entrepreneurs from time to time.

Biotech entrepreneurs are the backbone of biotech industry. They are the innovators with a vision that their idea will impact the life of masses for better. Biotech entrepreneurs start companies for the reasons given as under:

1. Biotech entrepreneurs believe that their ideas can solve a real-life problem of people around the world.
2. Biotech entrepreneurs are found to be altruistic in nature while starting their enterprise.

3. Financial rewards are also motivators to prove to the world that their discoveries can be commercial successes.

### 13.3.2 Assimilation of two distinctly different disciplines

Biotechnology is pure science, which when takes the form of an enterprise becomes commerce (a distinctly different discipline altogether). This intertwining of two disciplines can be a challenge for first time entrepreneurs. Scientific research requires academic skill in the subject while setting up biotechnology enterprise demands knowledge of economic conditions, decision making ability and risk-taking ability between a General entrepreneur and Biotech entrepreneur is as under:

**Table 13.1: Comparison between General and Biotech Entrepreneurs**

Basis	General Entrepreneur	Biotech Entrepreneur
Idea	Must be competitive	Must be competitive
Team work	Necessary and must be experienced	Necessary and must be experienced
Risk	Takes all risks with perseverance	Takes all risks with perseverance
Gestation period	Low to high depending on the type of enterprise	High
Degree of uncertainty	Present, but not scientific in nature	Uncertainty in business apart from other types carries inherent scientific uncertainty.
Capital requirements	Low to high depending on the type of enterprise	High
Relevance of academic qualification	Moderate to negligible	Very high
Regulatory framework	Moderate	High

### 13.3.3 Process of starting a Biotech enterprise

Starting an enterprise requires intense planning and does not happen without a proper roadmap in place. The element of 'chance' should be avoided and rationale should be present for every action taken while starting an enterprise. As the words of Louis Pasteur go, "chance only favors the prepared mind", an entrepreneur must be prepared for the outcome of his actions. This is true for all enterprises and also for biotech entrepreneurs. Following are the steps that are critical to starting a biotech enterprise:

#### **Step 1: Need assessment**

The entrepreneur should conduct a thorough assessment of the market demand for the product. The entrepreneur must be absolutely sure that there is a real market need for the product to be offered. Also, one has to be sure that the technology of interest is protected by intellectual property (IP). Finally, the entrepreneur needs to secure the assets, IP rights and assurances from the inventors and key personnel (in case the promoter is not the only one involved in the business).

#### **Step 2: Identification of founders and key personnel**

A new entrepreneur must look for like minded individuals who can join the team and bring the idea into reality. Generally, we see that a new entrepreneur works collectively with a team of people with expertise in diverse disciplines. Selecting this key group of people is a challenge, yet this group is indispensable to the success of an entrepreneurial idea.

#### **Step 3: Getting a legal expert**

This individual is a key partner. A legal advisor will be the individual the promoter will go to for advice and guidance. He will help the promoter move through the corporate and business issues during all the stages of establishing and growing his company.

#### **Step 4: Incorporation as a Limited Company**

It is advisable for the entrepreneurs of Biotechnology based start ups to register their companies as Private Limited Companies under the provision of the Companies Act 2013. Due to the nature of the business that demands

high capital investment and an above average gestation period, a Limited enterprise would be the best fit for a Biotechnology Startup.

***Step 5: Design a marketing and business strategy***

A well-designed business and marketing strategy are the next requirements. It will not be possible to raise money unless it clearly describes the market problem and need for the product, how the new product will solve the need, how much money the new product will generate, how the fund generated will be utilised and the expected return on investment.

***Step 6: After the seed capital is raised the technology development should be the focus***

It is important to highlight the key product development milestones in biotechnology ventures. The product is the pivot in a biotech enterprise and hence innovation in the same must be consistent to keep the market sentiments positive to establish and grow.

## **13.4 CONCEPT OF IPR**

The proprietary aspect is the key feature of biotechnology of modern times. In the past, innovations in biotechnology came out only of publicly funded laboratories. In present times, biotech innovations are well protected within legal framework of Intellectual Property Rights (IPR).

With the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement of World Trade Organisation (WTO), the Intellectual Property Rights attained the authority to enforce the law internationally. According to TRIPS, the intellectual property rights are:

**Copyright and Related Rights**

1. Rights of artists, painters, musicians, sculptors, photographers and authors for copyright in their works.
2. Rights of computer programmes, whether in source or object code for a copyright in their programmes and compilation of data.
3. Rights of performers, producers of phonograms and broadcasting organisations in respect of fixation on their programmes for copyright in their work.

4. Right of traders in their trademarks.
5. Right of manufacturers and producers on geographical indication in relation to such products and produce.
6. Right of designers for their distinctive design striking to the eye.
7. Right of the inventor for patent of his/her invention.
8. Rights of plant breeders and farmers.
9. Rights of biological diversity.
10. Right of computer technologist for their layout design of integrated circuits.
11. Right of businessmen for protection of their undisclosed information on technology and management.

#### **13.4.1 The aspects of IPR involved in Biotechnology**

##### **(a) Patent**

The Patents Act 1970, along with the Patents Rules 1972, came into force on 20th April 1972, replacing the Indian Patents and Designs Act 1911. The Patents Act was largely based on the recommendations of the Ayyangar Committee Report headed by Justice N. Rajagopala Ayyangar. One of the recommendations was the allowance of only process patents with regard to the inventions relating to drugs, medicines, food and chemicals.

Later, India became signatory to many international arrangements with an objective of strengthening its patent law and coming in league with the modern world. One of the significant steps towards achieving this objective was becoming the member of the TRIPS system. Being a signatory to TRIPS, India was under a contractual obligation to amend its Patents Act to comply with its provisions. India had to meet the first set of requirements on 1 January 1995 to give a pipeline protection till the country starts granting product patent.

On 26 March 1999, Patents (Amendment) Act, 1999 came into force retrospective effect from 1 January 1995. The second phase of amendment was brought in by the Patents (Amendment) Act, 2002 which came into force on

20 May 2003. The third amendment to the Patents Act, 1970 came by way of Patents (Amendment) Ordinance, 2004, which was later replaced by The Patent (Amendment) Act, 2005, and Patents (Amendment) Rules, 2006 with retrospective effect from 1 January 2005. With the third amendment, India met with the international obligations under the TRIPS. The most recent amendment The Patent (Amendment) Rules 2020 (“Amended Rules”) have come into force on 20 October 2020. By way of the Amended Rules, certain amendments have been made to Form 27 (“New Form 27”). Form 27 is the form prescribed for patentees and licensees to furnish statements regarding working of their patent in India.

Section 5, an important section of the Indian Patent Act, 1970 was deleted by the 2005 Amendment Act to allow product patents in the area of biotechnology, chemicals and pharmaceuticals. The basic criteria for a patent to be granted are novelty, non-obviousness (inventive step) and utility. For a patent to be granted in India, it should not be covered in the negative list in Section 3 which provides an extensive list of what are not considered as inventions under the Indian Patents Act. The inventions related to DNA molecules or sequences must not be contrary to public order and morality.

The biotechnology industry is devoted to the development of commercially valuable therapeutic, biochemical and pharmaceutical products and processes among others. Many of these products and processes revolve around the manipulation of DNA molecules and their encoded proteins. In the last thirty years, great strides have been made in the field of biotechnology and particularly in recombinant DNA research. However, with this progress has come a degree of uncertainty regarding the obviousness of certain biotechnological inventions.

For example, procedures of cloning genes and transporting them between organisms have become common place. The ready accessibility of these methods along with the central doctrine of molecular biology, i.e., DNA is transcribed into RNA, which in turn is translated into functional or structural protein molecules, has created a somewhat disarrayed legal structure.



In India, only inventions are patentable while discoveries are not. There is a clear distinction between inventions and discoveries as the law specifies that only inventions create patentable subject matter. Indian patent law provides for a demonstrative list where it has mentioned the subjects that are not patentable. Any subject matter, which does not fall within the domains of the demonstrated list, does establish a patentable subject matter. The list has been updated and altered to comply with the provisions of the TRIPS.

### **(b) Plant Breeder's Rights and Farmer's Variety Act**

Plant breeder's rights (PBRs) are used to protect new varieties of plants by giving exclusive commercial rights for about 20–25 years to market a new variety or its reproductive material. The variety must be novel, distinct, uniform and stable. This protection stops anyone from growing or selling the variety without the permission of owner. Exceptions may be made, however, for both research and the use of seed saved by a farmer for replanting.

### **(c) Trademark**

The Trademark Act, 1999 under Section 2 (zb) defines 'trade mark' as "a mark capable of being represented graphically and which is capable of distinguishing the goods or services of one person from those of others and may include shape of goods, their packaging and combination of colours..." Besides, the Act also provided for the definition of 'mark' under Section 2(m), which enumerates a mark to include a device, brand, heading, label, ticket, name, signature, word, letter, numeral, shape of goods, packaging or combination of colours or any combination thereof.

#### **Two essential ingredients for Trademark registration**

1. The mark is capable of being represented graphically.
2. Capable of distinguishing goods and services of one person from those of others.

### **(d) Copyright**

Copyright is a right given by the law to the creator of literary, dramatic, musical and artistic work and the producers of cinematograph films and sound recordings.

In fact, it is a bundle of rights including, *inter alia*, rights of reproduction, communication to the public, adaptation and translation of the work. There could be slight distinctions in the alignment of the rights dependent on the work.

Under certain conditions, a great deal of research, study, review and critical reports, along with works in library and schools and in the legislatures, is acceptable without specific permission of the copyright owners. In order to protect the interests of users, some exclusions have been prescribed in respect of specific uses of works enjoying copyright. Some of the exclusions are the uses of the work—

- (a) for the purpose of research or private study
- (b) for criticism or review
- (c) for reporting current events
- (d) for judicial proceeding
- (e) for performance by an amateur club or society if the performance is given to a non-paying audience
- (f) for the making of sound recordings of literary, dramatic or musical works under certain conditions

### **(e) Trade Secrets**

For being a signatory to the Agreement on TRIPs, India is obligated to protect undisclosed information. However, because Member States are allowed to have a *sui generis* (that is, something that is unique or different) mechanism in place as provided under Article 10b of the Paris Convention and Articles 39(2) and 39(3), Indian Courts have chosen to apply common law principles to protect such information. India does not have a specific legislation that is codified to protect Trade Secrets.

In lieu of a statute, Trade Secrets are capable of being considered within the framework of contract, competition and intellectual property laws simultaneously. They can be protected by way of restrictive covenants, non-disclosure agreements and other contractual means. Besides, Trade Secrets can also be protected by an action against misappropriation under common law, wherein misappropriation of trade secrets may occur by way of breach of an obligation of confidence, whether arising impliedly or expressly, as well as theft.

## 13.5 Biopiracy

When there is commercial exploitation of biochemicals or genetic materials which occur naturally, it is known as biopiracy. Generally, indigenous people have traditional understanding of biological features and genetic diversity of the natural environment passed on from one generation to another. Few of the traditional knowledge relevant to global survival has the elements listed below:

1. Farming or agriculture
2. Medicinal plants
3. Varieties of food crops

There have been cases of infringement of rights towards traditional materials in recent times. Here are some examples:

1. A case of biopiracy by multinational corporations is that of the Neem tree of India. The patent for Neem was granted by the European Patent Office to the United States Department of Agriculture and the Chemical Multinational, W.R. Grace, in 1995. This was opposed by the International Federation of Organic Agriculture Movement and the Green Party in European Parliament. In 2000, the European Patent Office revoked the patent.
2. In 1995, two expatriate Indians at the University of Mississippi Medical Centre were granted U.S. Patent 5,401,504 on 'Use of Turmeric in Wound Healing'. The claim covered 'A method of promoting healing of a wound by administering turmeric to a patient afflicted with wound'. This patent also granted them the exclusive right to sell and distribute turmeric. In 1996, The Council of Scientific and Industrial Research (CSIR), India, New Delhi, requested the US Patent and Trademark Office (USPTO) to revoke the patent on the grounds of existence of prior art. It could provide documentary evidence of traditional knowledge including ancient Sanskrit text and a paper published in 1953 in the Journal of the Indian Medical Association that proved that turmeric was already used by Indians for healing. The patent was revoked in 1997 after ascertaining that there was no novelty.

3. In late 1997, an American company RiceTec Inc, was granted a patent by the US patent office to call the aromatic rice grown outside India 'Basmati'. RiceTec Inc had been trying to enter the international Basmati market with brands like 'Kasmati' and 'Texmati' described as Basmati-type rice with minimal success. Basmati rice means the 'queen of fragrance or the perfumed one.' This type of rice has been grown in the foothills of the Himalayas for thousands of years. RiceTec's usage of the name Basmati for rice which was derived from Indian rice but not grown in India, and hence not of the same quality as Basmati, would have led to the violation of the concept of Geographical Identification (GI) and would have been a dishonesty to the consumers. However, all the patent rights that were granted were rejected.

In order to curb the biopiracy of traditional medicines, Traditional Knowledge Digital Library (TKDL) has been set up which is a pioneering initiative of India to prevent the misappropriation of country's traditional medicinal knowledge at International Patent Offices. Its beginning dates back to the Indian effort on revocation of the patent on wound healing properties of turmeric at the USPTO.

## SUMMARY

- Entrepreneur is an individual who undertakes an activity foreseeing business opportunity. They organise resources needed for starting the enterprise and also bear the risk involved in the process.
- Entrepreneurship is widely regarded as the best way to augment the growth of an economy. Entrepreneurs have played a significant role in developing some of the best economies of the world like that of USA and Japan. In India also we have had several communities who have played the significant role of entrepreneurs for the economic development of our nation.
- Entrepreneurs are seen to display certain inherent qualities like that of initiative, knowledge and skill, risk-taker, adaptability, self-confidence and they are also the wealth creators.

- The two terms—entrepreneur and intrapreneur, are often used interchangeably. But each has a distinctive definition. An entrepreneur is a person who takes risks to start a business venture in order to earn profit. On the other hand, an intrapreneur is an employee of an organisation who promotes innovation among the employees of the organisation.
- In entrepreneurial terminology, the term ‘Startup’ has become a popular word. A startup should be working towards innovation or improvement of the existing products, services and processes and should have the potential to generate employment and to create wealth. An entity formed by splitting up or reconstruction of an existing business shall not be considered a ‘Startup’.
- There are seven sources of starting a new venture viz. Personal Investment, Venture Capital, Angel Investors, Business Incubators, Government Grant Subsidy and Bank Loans.
- Biotechnology entrepreneurship consists of all the activities that an entrepreneur does to build and sustain an enterprise based on biotechnological innovation. It is an enterprise built by the amalgamation of science and business.
- There are six steps that are critical to starting a biotech enterprise, these are—Need assessment, Identification of founders and key personnel, Getting a legal expert, Incorporate the company as a Limited Company, Design a marketing and business strategy, and Focus on technology development.
- The proprietary aspect is the key feature of biotechnology in modern times. In the past, innovations in biotechnology came out only of publicly funded laboratories. In present times, biotech innovations are well protected within legal framework of Intellectual Property Rights (IPR). Aspects of IPR involved in biotechnology are Patent, Plant Breeder’s rights and Farmer’s Variety Act, Trademark, Copyright and Trade-secrets.
- Biopiracy is a major issue in efforts to commercialise biotechnological knowledge. When there is commercial exploitation of biochemicals or genetic materials which occur naturally, it is known as biopiracy. Generally, indigenous people have traditional understanding of biological features and genetic diversity of the natural environment passed on from one generation to another. There have been cases of infringement of rights towards traditional materials in recent times. A case of biopiracy by multinational corporations is that of the Neem tree of India. Another case was when patent was granted to researchers for the use of turmeric in wound healing, which was revoked later. Yet another case was when rice similar to Basmati was granted patent in USA, which was also revoked later.

- In order to curb the biopiracy of traditional medicines, Traditional Knowledge Digital Library (TKDL) has been set up which is a pioneering initiative of India to prevent misappropriation of country's traditional medicinal knowledge at International Patent Offices.

## EXERCISES

1. Define the term 'entrepreneurship'. Describe its importance.
2. What are the qualities of an entrepreneur?
3. Differentiate between entrepreneur and intrapreneur.
4. What are the steps of preparing a feasibility report?
5. Define a 'start-up'. What are the sources of funds for a new venture?
6. Elaborate the significance of a Biotechnology Entrepreneur.
7. Identify the similarities and differences between General Entrepreneur and Biotechnology Entrepreneur.
8. Explain the process of starting a Biotech Enterprise.
9. Explain the concept of IPR and aspect of IPR in Biotechnology.
10. Explain the role of IPR in Biotechnology Enterprise.
11. What are the three central criteria for grant of Patents of any scientific inventions?
12. 'Angel' usually provide what type of financing?
  - (a) Debt
  - (b) Equity
  - (c) Stock Sales
  - (d) None of the above
13. A patent is granted for a specified amount of time because of the assumption:
  - (a) That during this time, the firm will cover its development costs
  - (b) That firm will earn a sufficient profit during this period
  - (c) To limit the monopoly of the firm
  - (d) That it will stimulate the idea and development of a better product



14. A short-term, internal source of funds can be obtained by reducing all of the following EXCEPT \_\_\_\_\_.
- (a) short-term assets
  - (b) cash
  - (c) fixed assets
  - (d) Inventory
15. A typical researcher entrepreneur usually \_\_\_\_\_.
- (a) is highly creative and enjoys the process of research
  - (b) does not encourage change
  - (c) is not willing to take risk
  - (d) dislikes change
16. Which of the following elements is NOT an important element of the financial data and projections section of a business plan?
- (a) SWOT analysis
  - (b) Projected income statements
  - (c) Break-even analysis
  - (d) Cost controls
17. Which of the following cannot be covered under the copyright protection?
- (a) Computer software
  - (b) Computer hardware
  - (c) Poems and songs
  - (d) Models and sculpture
18. Which of the following is false?
- (a) A business plan is often prepared by an existing company to ensure that growth is properly managed.
  - (b) A business plan is usually not required when obtaining finance for a startup.
  - (c) If a business plan is completed for a start-up, it may help the entrepreneur avoid costly mistakes.
  - (d) All of the above.
19. Which of the statements is/are true with respect to entrepreneurship?
- (i) Entrepreneur is an individual who undertakes an activity foreseeing business opportunity.
  - (ii) He/She organises resources needed for starting the enterprise and also bears the risk involved in the process.

- (iii) There are three prominent roles that an entrepreneur fulfils that of an innovator, organiser and a risk bearer.

Options:

- (a) Only (i)
  - (b) Only (i) and (ii)
  - (c) Only (i) and (iii)
  - (d) (i), (ii) and (iii) are true
20. Seed capital assistance is \_\_\_\_\_.
- (a) a long-term assistance.
  - (b) initial assistance
  - (c) a help for the purchase of seeds.
  - (d) a short-term assistance.
21. Which one of the following is a pioneering initiative of India to prevent misappropriation of country's traditional medicinal knowledge at International Patent Offices?
- (a) Traditional Knowledge Digital Library (TKDL)
  - (b) National Digital Library of India (NDLI)
  - (c) Digital Library of Open Access Books (DOAB)
  - (d) Universal Digital Library

*Note*

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