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Medical Device Development – A Novel Experience in Patenting and Technology Transfer

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The Biomedical Technology Wing of Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST) was set up to develop appropriate technologies to meet the health care needs of India with a variety of facilities for research and development in biomaterials and medical devices. The institute has developed and transferred 12 technologies for commercial production and six others are in advanced stages of transfer. Apart from the direct savings in foreign exchange, the lower price of these competitive indigenous products has in every instance, helped to keep down the price of the imported counterparts. Novel methods of technology transfer have been developed to ensure successful commercialization in the country, where a medical devices industry hardly existed. The strategies using novel approaches and their development and changes with time are described in the paper.

Keywords: Technology development, technology transfer, licensing policies, techno-prove facility

The Sree Chitra Tirunal Institute for Medical Sciences and Technology, combines specialized medical care with development of medical devices and biomaterials, while providing training in advanced medical specialties, public health and biomedical engineering and technology and serves as a tertiary referral centre for the diseases of heart and brain as well as a teaching hospital.

The Institute's Biomedical Technology Wing (BMT Wing) has developed several technologies and successfully commercialized them. The third wing of the institute, the Achutha Menon Centre for Health Science Studies (AMC) has made significant impact in the area of health science studies in the country, especially in training, surveys, networking and research. The AMC has been recognized as a Centre of Excellence for Public Health Training by the Ministry of Health, Government of India.

Technology Development

In the BMT wing, a team of 30 scientists and engineers along with the supporting staff are working in multi-disciplinary areas covering biomaterials development, processing and characterization to medical device development, testing and evaluation.

The institute has developed and transferred 12 technologies for commercial production and six others are in advanced stages of transfer. The notable ones are listed in Table 1.

The commercial success of these technologies has brought in monetary returns and social benefits. Apart from direct savings in foreign exchange, the lower price of these competitive indigenous products has in every instance, helped to keep down the price of the imported counterparts. This has also led to an

Table 1—Technology transfers for commercialization

Item	Relevant IPR (Indian patent no/ application numbers and design registrations)
Blood collection & storage bags	Patent–160621 (15/10/84) Design–153737 (01/12/83)
Heart valve	Patent-180653 (28/8/92) Design-15373 (01/12/83) Design-153739 (01/12/83)
Membrane oxygenator	Application number 1153/MAS/1999
Centrifugal blood pump	Filed in 2004
Hydrocephalus shunt	Patent-180185 (19/11/91)
Concentric needle electrode	Design-180028 (29/7/99)
Homogenous hydroxyapatite powder	Patent-181625 (12/02/96)
Fibrin glue	Patent-188763 (17/5/99)
Fibrin sheet	Patent-188421 (24/12/98)
Bis-GMA (dental application)	Patent-193196 (21/7/97)
Improved dental paste	Patent-180414 (18/5/93)

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increased participation and investment by industries from the R&D stage itself. The institute holds 54 patents and 13 design registrations; another 49 patent patent applications are under processing.

The institute together with its industrial partner TTK Healthcare Ltd has successfully developed and commercialized the artificial heart valve. With over 15,000 implants so far, the product is being used in over 100 centres in the country and meets over 35% of the market need.

Patent protection for its technologies has always been on the agenda of the institute. However, it was important to develop simultaneously novel methods of technology transfer to ensure successful commercialization in the country, where a medical device industry hardly existed. Various strategies using novel approaches and their development has since then been a major focus area.

Patenting in the Early Days

During the early 1980s, the mandate was to develop commercially viable technologies as cost effective import substitutes by reverse engineering. The strategy used was to protect the process know-how with an Indian patent by utilizing the merits of the 1970 Patent Act and thus ensure that industrial partners would not be troubled by other competitors within the country or from abroad. Where the processes were indigenously developed, had good innovative features; foreign patents, especially in developed countries were also filed. However, due to the non-tariff barriers imposed by medical device regulatory authorities in developed nations and a lack of knowledge base within the country, made commercialization in these countries almost impossible then.

Early patents filed were for the blood bag, heart valve, soft shell blood oxygenator and cardiotomy reservoir and their components. The early strategy was therefore, more of a precautionary measure against commercial competition from rivals claiming infringement. It also protected the technologies from any unhealthy competition and low cost imitations within the country.

Current Patenting Approaches

From mid 1990s, however, there was a shift in the research emphasis to an innovative product development mode. With the research being more basic, the studies inevitably generated scientific papers worthy of publication in international journals. The institute then followed a policy of ensuring that patentable concepts and research work are first protected by a patent filing before being published. This more or less ensured the protection of IPR, when innovations eventually got converted into commercial products.

Since the turn of the millennium, the institute has matured into an advanced centre for R&D in the areas of biomaterials and medical devices. With the globalization of the country's economy and the new WTO patent regime coming into play, the transition to a new strategy in IPR has become necessary.

The new policies and procedure being evolved now will exploit the Patent Cooperation Treaty (PCT) system to gain priority and IPR in the international market place. In 2000, the estimated one and a half million different medical devices available in the market represented over US $145 billion. With innovation and rapid advancement of technologies, medical devices are currently one of the fastest growing industries, and the global market figure for 2006 is expected to exceed US $260 billion[1]. Eighty five percent of the world market is currently covered by USA, Europe and Japan, while the market size in India is hardly $1.5 billion. Hence the R&D strategy has to shift to development of innovative products at an international level, if IPR is to be leveraged and commercialized effectively. Since international patenting is expensive exercise, this requires (a) an extensive patent search and reviewing of prior art, (b) getting a market analysis of the worth of the invention vis-à-vis the international scenario for the application, (c) selecting and filing in appropriate countries where market potential is maximum for the invention and (d) understanding the medical device regulatory scenario in each of these countries for effective introduction.

To convert the IPR into real wealth calls for marketing it on a global scale to make certain that the returns from IPR generated can be maximized quickly. This in turns calls for a considerable amount of planning and hard work to develop the concepts from the time the patent is filed to the time an entrepreneur can be convinced of its potential with detailed data on the product and its efficacy.

Medical devices require considerable amount of testing for safety and efficacy before the workability of the concept can be conclusively established. PCT allows for 30 months time for this development activity to be completed and hence has great potential for exploitation of medical device developments.

Problems in Technology Transfer – Laboratory to Industry

The first technology developed in the institute, the process know-how for the 'blood-bag' was directly transferred to an entrepreneur from the laboratory level. Though training for industry personnel was imparted in the laboratories, lack of experience on both sides in the art of scaling up and process development to a manufacturing level led to a number of problems that took considerable effort and time to resolve. When the next technology was getting ready, institute adopted a new concept of 'Technology Proving'. This phase provides a platform for an organized transfer of technology to the industrial partner.

The Concept of Technology Proving

Effective commercialization requires high quality products, which are backed by good design and appropriate manufacturing technology. This is especially true of medical devices, where the users are highly quality conscious. Under Indian conditions, transfer of technology directly from the laboratory to a production plant results in numerous problems. One of the main factors is the limited strength of R&D personnel in industry and the relative inexperience on both sides in scaling up from laboratory level. Hence, plant-to-plant transfer has been the preferred mode of technology transfer so far. Problems multiply in medical device industry due to mandatory requirements of implementing Good Manufacturing Practices (GMP) for the production process.

Setting up of the 'Techno-Prove Facility' (TPF) in BMT wing of the institute in 1988 was an effective mechanism in overcoming these limitations and for successfully completing the technology transfer process. Products developed by various in-house laboratories undergo scale-up here with the sponsorship of an industry under the strict supervision of the development group. The advantages of this facility are many, both for the industry and the institute.

1 With minimal investment, industry can observe technology in operation and satisfy themselves that it is viable. Further, the product is available for market seeding to determine its market acceptance, saleable price and demand estimation.
2 The industry can considerably reduce the time lag between signing of technology transfer agreement and introduction of the product. Even while the plant is under construction, the product will be available in the market with their brand name.
3 Evaluation of all the equipments is carried out during production and necessary improvements can be made while ordering the equipments for the final plant.
4 A fully trained core group is ready when commercial production is started.
5 Vendors for some of the fabricated components can be established. Since the batch to batch testing of raw materials and components is mandatory, this will help both economically as well as in conserving time. The industry can use this fully qualified vendor without further problems.
6 The development group can strictly control quality of the product due to their active involvement.
7 Depending on feedback, further improvements can be carried out more easily due to the availability of the development team.

At the end of scale-up production, industry gets detailed technology transfer documents consisting of testing and validation documents, process details and quality assurance documents, equipment, test set up, jigs, fixtures etc specifically developed for the product / process, user documents as well as training and technical assistance to set up industrial facility.

The TPF infrastructure is designed such that once the raw materials and components are taken inside, all processes including terminal sterilization are carried out.

The following successful scaling-up production processes were carried out from 1989 to 2002

a. 1250 pairs of bubble oxygenator and cardiotomy reservoir under a project sponsored by SPIC Science Foundation, Madras
b. 200 chest drainage systems by Peninsula Polymers Ltd, Thiruvananthapuram
c. 2600 hydrocephalus shunts under project sponsored by Hindustan Latex Ltd, Thiruvananthapuram
d. 1000 artificial heart valves by TTK Pharma, Madras
e. 1800 concentric needle electrodes, under the project sponsored by South India Drugs & Devices Pvt Ltd, Madras
f. Membrane oxygenator, under the project sponsored by South India Drugs & Devices Pvt Ltd, Madras

Licensing Policies

Over the last two years, the institute has had to deal with entrepreneurs with differing demands, some of which are specific to the technology or product that is being commercialized. Hence, there is a need to tailor the licensing terms and the technology transfer mechanism for each product and licensee, However, in general following three strategies are used:

Non-Exclusive Licence

The general policy is to award non-exclusive licences to industries for the commercial production of biomedical technologies, which have been wholly developed and funded by the institute. This gives the freedom to re-license the technology in case of poor performance by the first industrial partner or in case the market demand justifies further licenses. As a general policy, the aim is to avoid unhealthy competition, which makes the inventions unviable. Where the industrial partner is not aggressive enough to meet market demands there is a definite need to utilize freedom for further licensing.

Exclusive Licence

A technology development activity that is totally sponsored by an industry partner is normally awarded an exclusive license. In such a case, the IPR ownership is jointly shared with the sponsor. The end product of such R&D efforts would be exclusively licensed to the sponsor for commercial production. For further licensing to third parties, a joint licensing strategy is agreed upon.

Limited Exclusive License

Where the sponsor partially funds the development like in the technology proving exercise, a limited exclusivity for 3 to 5 years is granted with a rider on commercialization within a stipulated time (12 to 15 months) of agreement, failing which the institute is free to re-license the know-how to a third party without any liability.

The licence fee and royalty terms are based on the guidelines provided by United Nations Industrial Development Organization (UNIDO) for 'Transfer of Technologies', which takes into consideration the market demand, value of the new product and estimated investment required for setting up a production plant.

Conclusion

Over the last 3 decades of R&D in the area of medical devices and biomaterials, the institute has had to innovate constantly in process development and in patenting and technology transfer practices. With the international scenario in the country changing rapidly, continuous policy and procedural changes are essential to remain competitive.

References

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