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Original Article

Advancements In Technology Transfer: Analyzing Models, IP Rights and Digital Disruption

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ABSTRACT

Technology transfer is a critical process that facilitates the movement of innovations and knowledge from research institutions to industry, thereby driving economic growth and technological advancement. This review provides an in-depth analysis of various models of technology transfer, including linear, interactive, and network models, and examines their effectiveness in different contexts. The role of intellectual property rights (IPR) is highlighted as a fundamental aspect in protecting innovations and ensuring fair value distribution among stakeholders. Furthermore, the paper explores the impact of digital transformation on technology transfer processes, emphasizing how advancements in digital tools, such as artificial intelligence, big data, and blockchain, have redefined traditional mechanisms. Digital platforms are enabling faster and more efficient knowledge dissemination, fostering global collaborations, and providing new opportunities for startups and small enterprises. However, challenges related to data security, privacy, and regulatory compliance are also discussed. This review aims to provide a comprehensive overview of the evolving landscape of technology transfer, offering insights into future directions and potential areas for policy intervention to maximize the benefits of technology diffusion in the digital age.

Keywords: Technology, Innovations, Analysis, Intellectual Property Rights (IPR).

INTRODUCTION

Technology Transfer:

It is a sensible procedure that comprises professional experience, the transfer of a process, and the associated paperwork between the locations of different manufacturers and the same manufacturer [1]. In the current corporate environment, there is a greater interest in the successful utilization of a company's technological assets through technology transfer. Globalization of commerce, the liberalization of many nations' economic systems, and the push for intellectual property protection.

following the World Trade Organization's (WTO) founding are some of the factors that have made international technology transfer easier. Due to the combined effects of these variables, technology commercial transfer has grown in importance within the context of international business3.Organizations are beginning to recognize the value of technology and how to manage it as a critical strategic component. Organizations should employ technology to help them compete in the global economy. As a result, organizations need to manage technology and its related issues well. The transfer of the best technology to the organization is one of the crucial factors to be taken into account while managing technology. The technology must be moved from a developer environment to a user environment as a result. Decision-makers may benefit from knowing about the technology that an organization uses, the technologies that other organizations have access to, and the technologies that rival organizations utilize. But from a development standpoint, technology transfer has always been important. Mansfield (1975), more than three decades ago, noted that technology transfer is one of the fundamental processes that influences the economic performance of nations and firms.

In order to the successful transfer the following requirement should be met:

Both the sending unit (SU) and the receiving unit (RU) should have comparable facilities and equipment. It is necessary to communicate protocols, reports, specifications, critical process parameters, and supporting data from the sending unit [SU] to the receiving unit [RU].

Terminology: An active pharmaceutical ingredient, or API, is any chemical or combination of substances

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that, when consumed, becomes an active ingredient of that pharmaceutical action and is meant to treat, prevent, or otherwise alter the body's structure and function. [2]

Good Manufacturing Practices (GMP):

A component of quality assurance that guarantees the regular production and control of pharmaceutical products to the proper standards of quality for the intended purposes.

Process validation: This is the verified evidence that provides a high degree of confidence that a particular procedure will consistently result in a product that meets its defined action and quality requirement.

Quality Assurance (QA): This is a catch-all word encompassing a range of problems that could negatively impact a product's quality in one or more ways.It is the culmination of all efforts made to ensure that pharmaceutical goods meet the standards necessary for the uses for which they are intended [3].

Quality control (QC**)**: This process confirms that pharmaceutical products adhere to specified requirements for identity, potency, purity, and other characteristics. It includes requirements setting, testing, sampling, and gaining analytical clearance for packing materials, finished goods, intermediates and raw materials.

Quality risk management (QRM): The systematic process of identifying, addressing, sharing, and evaluating threats to the quality of pharmaceutical products throughout their life cycle.

Sending unit [SU]: The disciplines inside an organization that are necessary for the transmission of a specific product, procedure, or method are known as the sending unit.

Receiving unit (RU): The disciplines involved at the organisation where the transfer of a specific product, process, or method is anticipated [4]

Standard Operating Procedure [SOP]: a formal, authorized protocol that is in writing and offers instructions on how to carry out duties that aren't necessarily connected to a specific material or product.

Technology Transfer Report. formal document that details the procedures, requirements, conclusions, and conclusion of a specific technology transfer project. Validation is the process of proving and documenting that a method, process, or strategy genuinely and reliably produces the intended results.

Acceptance criteria: quantifiable criteria that show whether test findings are satisfactory.

Bracketing: An experimental setup wherein only the extremes of, say, dosage strength, are tested. It is assumed by the design that the extremes will accurately represent any samples that fall between them [5].

Change Control [C/C]: Change control (C/C) is a formal process in which qualified representatives of pertinent disciplines assess changes that are being considered or that may have an effect on a validated state. Finding out what has to be done to make sure the system is maintained in a validated form is the aim.

A critical control point: A critical control point, or CCP, is a point in time when control measures can be put in place to eliminate, reduce, or eliminate a risk to a level appropriate for pharmaceutical quality.

Drug Master File [DMF]: A drug master file (DMF) provides comprehensive information about a specific facility, process, or product to the drug regulatory authority. This information is intended to be included in the application for marketing authorization. [6]

Gap analysis: Finding the crucial elements of a process that are present in the transmitting unit but not in the receiving unit is known as gap analysis. Inter-company transfer: The sharing of technology among multiple companies' sites.

In-Process Control [IPC]: In-process control, or IPC, refers to audits conducted during manufacturing to keep an eye on and uphold quality standards. The procedure ought to be modified as necessary to guarantee that the final result meets its requirements. A component of process control could alternatively be thought of as equipment or environment control. Testing is the process of ensuring that the installations used in a manufacturing process—such as machinery, measurement tools, utilities, and production spaces—are appropriately selected, installed, and operational in accordance with established standards.

Performance Qualification [PQ]: Documented evidence that the device or system operates consistently and reliably over a prolonged period of time within predetermined parameters and requirements.

Technology transfer [TOT]: A methodical process that manages the transfer of an established process, along with its documentation and expert knowledge, to a location that can replicate the process and its

supporting operations at a predefined degree of capability.

The VMP, or validation master plan:

This is an extensive document that functions as the project's overall validation approach. It also gives a summary of the approach and mindset of the company, which is used to decide if performance is sufficient. It describes the scope of the validation work to be done, provides information on the manufacturer's validation work program, and includes the completion timelines. It also describes the responsibilities of those executing the plan [9].

Methodology [or plan] for validation [VP]: A summary of the actions to be performed in the course of a validation, together with the prerequisites for approving a manufacturing process—or a component for regular usage.

IMPORTANCE OF TECHNOLOGY TRANSFER IN THE PHARMACEUTICAL INDUSTRY:

- To filter through the different information that was gathered throughout research and development in order to clarify what is needed to transfer technology from actual manufacturing to R&D.
- To clarify the information required for the technology of current goods to be transferred between different manufacturing locations.
- To facilitate seamless technology transfer, the following examples highlight particular protocols and areas of concern for the two types of technology transfer mentioned above. This covers the transfer of technology pertaining to post-marketing modifications in manufacturing facilities as well as the transfer of technology through research and development and the production of drug substances or drug products. [3,4]

GOALS OF TECHNOLOGY TRANSFER:

1) In order to realize product realization, product and process information must be transferred across and within manufacturing facilities. The manufacturing process, control strategy method, validation technique, and continuous improvement approach are all built upon this understanding.
2) The developmental life cycle that leads to successful commercial manufacturing includes TT as a crucial stage. should utilize all of the information acquired as the foundation for the manufacturing control strategy, the process qualification methodology, and continuous improvement initiatives.
3) The transfer of information about products, processes, and analytical methods between development and manufacturing locations.
4) To make sure that process and parameter variability are sufficient and under control given the demands of a commercial production environment.
5) To confirm that the development-phase parameters remain within the designated design space and are modified upon scale-up.

IMPORTANCE OF TECHNOLOGY TRANSFER:

For research and development to continue to benefit society, technology transfer is essential.

1) In the pharmaceutical sector, dosage form design must be scaled up at multiple stages. For example, a pilot batch weighing between 0.5 and 2 kg can be scaled up to 5/10 kg rather than 20/100 kg. Usually, the production scale is between 200 and 1000 kilogram. It entails using bigger equipment to manufacture pharmaceutical items in batches larger than before.

2) Technology and expertise acquired during the small-scale development of products and processes are transferred as part of the scale-up process. Typically, research is conducted in small batches prior to production for a larger commercial batch. Technology transfer is essential for research endeavors to become large-scale commercial products, particularly when creating pharmaceuticals.

3) To clarify the information required to move technology from research and development to actual manufacturing by organizing the diverse data gathered during the process; To clarify the information required to move technology of current goods between different manufacturing locations.

4) The commercialization of innovations developed at universities is a crucial factor in economic growth, and universities have been instrumental in bringing novel concepts and products to the market. Technology transfer has the potential to boost regional economic development and growth, produce income for universities, and establish links between academia and business for research. Thus, advancement and dissemination of technology and

knowledge have been and will be essential for success in a variety of industries. [12]

The importance of technology transfer an appropriate transfer of manufacturing technologies to improve drug quality as intended during research and development to be a final product during manufacture is becoming more widely recognized in recent years. It also ensures stable quality transfer for a variety of reasons between the contract giver and contract acceptor during manufacture. [13]

ORGANIZATION OF TECHNOLOGY TRANSFER:

Since the most effective way to complete a technology transfer project successfully is always in a team environment. The core technology transfer team ought to be put into action as soon as executive management decides to move forward with the drug candidate's commercialization. The members of a typical technology transfer core team will probably represent various business divisions.

1. **Project Manager:** Responsible for overall oversight, coordinating, and updating management on progress. If more employees are needed, their position may be expanded along with the authority and duty that are assigned to them.
2. **Regulatory Affairs:** Regulatory Affairs is responsible for organizing the relevant regulatory filings, offering guidance on when approvals should be granted, reviewing the substance of filing material and responding to regulatory queries.
3. **Engineering:** To oversee and manage the construction, equipment purchase, installation, and qualification processes as well as coordinate related capital projects.
4. **Material management:** This category includes the departments in charge of supply chain management, resource allocation, strategic planning, and pure chasing. This person, or members, will assess and suggest the best production plan taking into account the corporation's tax benefits, business partnerships, and internal capabilities.
5. **Manufacturing operations:** To depict the production activities at the source and the destination. These delegates ought to have enough power to commit the people and equipment required to complete the project within the allocated budget and time frame.
6. **Research and Development:** To help with technical concerns and provide solutions. In addition to providing process expertise, this group is expected to oversee and manage the production trials at the receiving site. [18]

STEPS INVOLVED IN THE TECHNOLOGY TRANSFER PROCESS:

Understanding the process of the operations used, the critical and non-critical parameters of each operation, the production environment, the equipment, and the availability of the excipients should all be considered in the early stages of formulating a formulation.

(A) Development of technology by Research Phase

(a) R&D develops the procedure design and excipient selection. R&D bases material selection and procedure design on the features of innovative products.

(b) R&D determines quality and specifications: A product's quality should match that of an innovative product.

Figure 1: Technology Transfer Process

(B) Technology transfer from R&D to production (Development Phase)

The product development laboratory receives a technology transfer dossier (TTD) document from R&D that includes all of the following formulation and drug product information:

(a) Master Formula Card (MFC): The product name, strength, generic name, MFC number, page number, effective date, shelf life, and market are all listed on the Master Formula Card (MFC).

(b) Master Packing Card: Provides details on the type of packaging, the material used to package, the stability profile, and the packaging's shelf life. **Master Formula:** Contains production guidelines and the order of formulation. (The order of the processes and the surroundings).

(c) Standard Test Procedures (STP) and Specifications: These provide information on the profile of active components and excipients, in-process parameters, product release specifications, and specifics of the final product.

(C) Optimization and Production. (Production Phase)

(a) Validation Research: Production commences following validation research that demonstrates the process's ability to stable the product using the transferred manufacturing formula. Validation, including performance certification, cleaning, and process validation, should be handled by the R&D department transmitting technology, not the production department receiving it.

(D) Technology Transfer Documentation

Generally understood to be a document outlining the technology transfer contents for the parties that are being transferred and transferred. Every stage of the technology transfer process, from R&D to production, needs to be recorded. Task assignments and responsibilities should also be made clear, as should the acceptance standards for any specific technology that is to be transferred. All technology transfer methods must have their documentation reviewed and approved by the quality assurance department.

(a) Development Report –The R&D department is in charge of the report's documentation, which is a file pertaining to technical development. This report is a crucial document that explains the quality design of drug compounds, together with their requirements and testing procedures. The development report can be utilized as a legitimate document for the new drug's quality design during pre-approval and inspection; it is not a requirement for the application for approval. The following are included in the development report:

(1) Information on the pharmaceutical industry's progress in developing novel drug ingredients and drug products, from the early stages of research to the application stage and eventual approval. Details on components and raw materials.

(2) Manufacturing process design.

(3) Modifications to significant processes' histories and control settings.

(4) Drug substance specifications and testing procedures.

(5) Validity of the specification range for significant tests, including dissolving and contents impurities.

(6) Results verifications.

(b) Technology Transfer Plan –The purpose of the technology transfer plan is to list the components and elements of the technology that needs to be transferred, as well as the specific steps involved in each transfer and the timetable for it. It also sets completion criteria for the transfer. Prior to the transfer taking effect, the transferring party must draft the plan and come to an understanding with the transferred party over its contents.

(c) Report - Technology transfer must be finished once data are collected in accordance with the technology plan and assessed to ensure that the preset standards for judgment are satisfied. The technology transfer report should be documented by both the transferred and the transferring parties.

(E) Exhibit – Manufacturing of display batches occurs following the acceptance of scale-up batches of the product. When it comes to exhibits, equipment and their procedures go hand in hand with larger batch numbers. This is carried out for regulatory agency filling purposes. 19

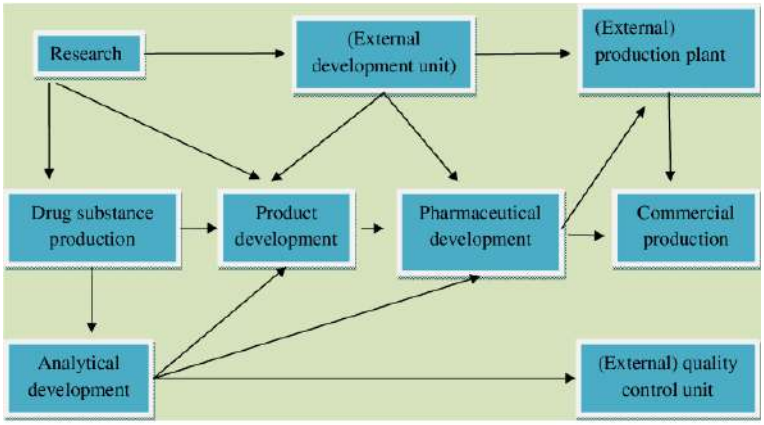

Figure 2: Flow Chart Technology Transfer

MODELS FOR TECHNOLOGY TRANSFER:

1. Qualitative Models:

a) The Bar-Zakay Model: Bar-Zakay (1971) created a fairly thorough TT model using a project management methodology. He separated the Search, Adaptation, Implementation, and Maintenance phases of the TT process. As seen in Figure 1, he illustrated the tasks, checkpoints, and decision-making moments in each of these phases. Bar-Zakay refers to the transferer as the "donor," and the lower half of the figure shows the activities and requirements of the transferee, or "recipient." This model outlines the tasks that must be completed in great detail and emphasizes the significance of both the transferor and the transferee developing the necessary skills to engage in technology forecasting, long-term planning, and the collection of project- related intelligence. The transferor is referred to in the model as a "donor," creating the impression that the owner of the technology is donating a priceless asset for charitable purposes! It is obvious that this is untrue, and using phrases like this has to be avoided. Another drawback of the Bar-Zakay model is that it is no longer very relevant because so many of the terms, activities, and ideas it expressed were part of the late 1960s and early 1970s, a time when most technology buyers were passive recipients who heavily relied on aid programs. It was also a time when the pace, direction, and extent of technology transfers were all determined in part by government constraints.

The following are some of the lessons that can be drawn from the Bar-Zakay model:

- The entire TT process, from "search" to "post-implementation" activities, needs to be thoroughly examined.
- TT projects need to be planned and carried out using a process-oriented approach.
- It's critical to establish decision points and milestones so that actions may be reinforced, errors can be fixed, and the project can end at any time14.

(b) The Behrman and Wallender Model: Multinational firms may find greater relevance in the seven-stage approach for foreign technology transfer put forward by Behrman and Wallender (1976).

These current phases are:

1. A manufacturing proposal, planning to determine the best location, and the creation of a business case with accurate resource assessments.
2. Selecting the technology to be transferred for product design.
3. Outlining specifics for the plant that will be built to manufacture the good as well as additional building and infrastructure development-related information.
4. Building a plant and beginning manufacturing.
5. Strengthening production systems and making necessary adjustments to the process and product to fit local conditions.
6. Using local expertise to improve the product technology conveyed.

Offering outside assistance to improve the transferor-transferee connection. This model's shortcoming is that the transferor designs the technology transfer project in the first three stages with the transferee's minimal input, which reinforces dependency. Nonetheless, there is a great deal of room for the transferee to absorb and advance both process and product technology in the fifth and sixth stages. This serves to highlight the fact that technology transfer is continuous and that a project cannot be deemed successful unless a system is in place to promote assimilation. The following are the things that this paradigm teaches us:

- The transferee must be included from the start in the design and execution of a technology transfer project.
- The start of production does not mark the conclusion of a technology transfer initiative.
- It is impossible to declare a technology transfer to have been successful unless clear procedures are in place to guarantee assimilation15.

(d) The Dahlman and Westphal Model:

Dahlman and Westphal (1981) conducted extensive research in the Republic of Korea and, drawing from their knowledge of rapidly industrializing Far Eastern nations in the 1980s, created a nine-stage process model that looks like this:

- Carry out pre-investment feasibility to gather information and carry out a techno-economic analysis to establish project viability.
- Carry out a preliminary identification of technologies needed, based on the feasibility study.
- Carry out basic engineering studies that involve the preparation of process flow diagrams, layouts, material and energy balances and other design

specifications of the plant and machinery and the core technology to be transferred.

- Carry out a detailed engineering study that involve the preparation of a detailed civil engineering plan for the facility, including construction and installation specifications and identification of the peripheral technology needed to make the transfer effective.
- Carry out the selection of suppliers for equipment and subcontracting services to assemble the plant and machinery and plan for the co-ordination of the work among various parties.
- Prepare and execute a training and education plan, in consultation with the suppliers of technology, for the workers who would be employed in the technology transfer project.
- Construct the plant.
- Commence operations.
- Develop trouble-shooting skills and put in place arrangements to solve design and operational problems as they arise, especially during the early years of operation.

This model, which places a strong focus on transferee involvement throughout the entire TT project, can be seen as an upgrade over the Behrman and Wallender model. The assumption that the transferee will have access to advanced engineering abilities is its main flaw. In a lot of poor nations, this could not be the case. Additionally, it gives negotiators and post-implementation integration initiatives relatively little thought. The following are some of the key lessons this paradigm imparts:

A sequential process view is the most effective way to study a TT project.

- Since TT initiatives necessitate significant resource commitments, no project should be started without a thorough feasibility analysis.
- From the start, the transferee should be involved in the planning process.
- Sound engineering and project18 development are crucial for transferees.

INTELLECTUAL PROPERTY RIGHTS IN TECHNOLOGY TRANSFER:

Since it is impossible to stop someone from using fresh knowledge even without the creator's permission, knowledge is usually non-excludable. A new technology's value increases the likelihood that it will be copied or mimicked, which could lessen the original inventor's prospective earnings and possibly eliminate the motivation to pursue inventive endeavors. By giving prosperous creators a brief monopoly over their creations, intellectual property rights, or IPRs, promote innovation. The returns on successful R&D investments are provided by the monopoly profits that follow; nevertheless, these returns must be substantial enough to offset the significant amount of unsuccessful R&D.

The non-rival nature of an innovation implies that its advantages will be maximized if it is made available to everyone at a marginal cost. Free access policies may assist society in the near term, but they will seriously undermine the motivation for new invention. However, overly restrictive intellectual property rights (IPRs) may prevent new knowledge from being shared effectively, which could impede growth to the point that more innovation is required to obtain access to current technology. IPR protection that is too lax has, in fact, encouraged knowledge spillovers from transnational companies (TNCs) and other domestic firms, which has boosted R&D activity in many nations. Overprotecting innovators can potentially result in a long-term monopoly even though it's not the best, aims to bring back the motivation to develop, which should promote long-term expansion and higher-quality products. Developed nations, which have a large pool of prospective innovators, have a tendency to choose IPR regimes that are reasonably robust in order to foster innovative and creative endeavors, which are viewed as a key driver of long-term economic progress. However, because R&D spending is concentrated in a small number of the richest nations in the world, most developed and developing nations have limited opportunities for truly innovative activities. Instead, most have adopted a different strategy, offering little to no intellectual property rights protection in order to facilitate the rapid diffusion of knowledge. Imitation has been a major source of technological growth for several of these countries. Stronger IPR protection is perceived as limiting output in the home economy and moving profits from native imitative enterprises to foreign firms, as opposed to promoting domestic inventive activity. The counterargument posits that enhanced intellectual property rights (IPR) protection can incentivize innovation and risk-taking, particularly in emerging economies. Conversely, nations with inadequate IPR ii protection are still reliant on

inefficient, dynamic businesses that engage in imitation and counterfeiting. To enhance the global IPR regime, the Uruguay Round (1986– 1994) trade negotiations produced the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). IPR protection is governed by the first worldwide and all-inclusive set of regulations, TRIPS. TRIPS lays out minimal requirements that must be fulfilled by a specific date. Copyrights and related rights, trademarks, geographical indications, industrial designs, patents, integrated circuit layout designs, and concealed information, such as test data and trade secrets, are among the topics covered.

CONCLUSION

Appropriate technology transfer is important to upgrade the quality of manufacturing products and ensure stable and high quality of the product. The technology transfer does not mean one- time actions taken by the transferring party toward the transferred party but means continuous information exchange between both parties to maintain the product manufacturing. In conclusion, this review underscores the intricate relationships between technology transfer models, intellectual property rights, and digital transformation. Effective technology transfer necessitates balanced models, robust intellectual property protection, and adaptability to digital advancements. Digital transformation has revolutionized technology transfer, enabled global collaboration and efficiency but introduced data security and privacy concerns. Future directions include developing adaptive models, strengthening intellectual property frameworks, and fostering industry-academia-government partnerships. Policymakers, businesses, and researchers must prioritize clarity, protection, and innovation to harness technology transfer's potential for economic growth and societal progress.

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