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Commercialisation of Innovations: A Case Study of Liposomal Formulations

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ABSTRACT

Liposomes are the potential drug delivery systems for various therapeutic categories. During the past 60 years, researchers have explored this drug delivery system which has resulted in a large pool of documents in terms of patents and publications. The paper's objective is to understand why after 60 years of extensive research with more than 50,000 patent documents and 35,000 research publications, only 17 products based on liposomes are commercially available. After detailed analysis, the authors found that the research publications and patent documents are primarily focused on the basic research aspects and have limited participation from the industry. Therefore, in this paper, it has been emphasised how the research projects on liposomes must re-orient its focus so that it leads to the commercialisation of liposomes. This paper also provides a comprehensive analysis of challenges and opportunities for researchers concerning various research areas of liposomes like manufacturing techniques, characterisations, stability, storage, pre-clinical and clinical evaluations, regulatory requirements as well as pharmaco-economic analysis.

Keywords: Liposomes; Patents; Research publications; Innovations; Regulatory

NOMENCLATURE

CAGR : Compound annual growth rate
CPC : Cooperative patent classification
WIPO : World intellectual property organisation
USFDA : United states food and drug administration
EMA : European medical agency
CDER : Center for drug evaluation and research

1. INTRODUCTION

Liposomes were reported in the 1960s, and the first liposome-based product was approved in 1990[1]. There are numerous advantages of liposomal drug delivery systems which have led to extensive academic research, and innumerable peer-reviewed publications on liposomes. Thousands of patent documents have been filed in different countries but the commercialisation of liposome-based products is meager in comparison to the knowledge base of liposome. The Vision Gain Report on Liposomal Drug Delivery Devices 2022-2032 estimated a global market of US$3,742.1 million in 2021 for liposomes. Further, it has predicted that the global market will see a CAGR of 10.04 % from 2022 to 2027[2,3]. This prediction could reach higher value if the research projects get aligned with the needs of the industry and may facilitate the commercialisation of liposome-based products.

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The research in liposomes represents an exciting field of science. A simple search on Pubmed with the search query "Liposomes" yielded around 4300 published documents. Out of this, approximately 3300 have authors with affiliation from the university. These numbers explicitly bring out the interest of researchers in Liposomes. In addition to research articles, the patent document search also resulted in astonishing figures. The term liposome was searched in "title, abstract, and claims" on a freely available patent database. This search query resulted in more than 50,000 patent documents. With these preliminary results also, it can be concluded that a large number of researchers are working on liposomes. However, the majority of these documents are based on basic research work. Drug delivery systems like Liposomes offer an interesting research field wherein drugs can be encapsulated in lipid vesicular systems to achieve improved pharmaceutical as well as biopharmaceutical attributes. These research projects are mainly funded by governments and provide preliminary work for further development which is much more complex.

The present paper comprises a detailed analysis of patent documents and research publications. The authors also underline the key features that are hindrances to the commercialisation of extensively researched liposomes at the basic research level. The patent and publication documents analysis explicitly brings out the this field is a popular research field, however poor translation of basic research into commercial products is an important area

to be discussed. Therefore, this paper also advocates the amalgamation of research projects with the technology development for commercialisation as a part of preliminary research work. Each research project should have a wider scope which must address the path from laboratory to commercialisation.

2. MATERIAL AND METHODS

2.1 Searching Patent Documents in the Field of Liposomes

A search on the freely available database www.lens.org was conducted. Lens is a global patent and scholarly knowledge database. This freely available database has patent search capabilities with advanced boolean functions, structured search, biological search, classification search, filtering, and sorting options to find the most relevant and important patents. It also has analytics tools that can generate different patent maps on a comprehensive collection of patents.

Simple search queries were used.

Search 1: Liposome was searched in Title, Abstract, and Claims and 52,950 patent documents were obtained.

Search 2: Liposome in Title or Abstract or Claims and University in Applicant name. 10,853 patent documents were shown.

2.2 Searching Published Articles in the Field of Liposomes

Research paper publication is an inherent part of research which is exercised by the scientific community. Liposome is a high-end area of research and one of the most extensively researched among the other new drug delivery systems. Therefore, the publications in the field of liposomes also provide a fair insight into the research activities. Table 1 provides the details of the search queries, database, and the results. The word "Liposomes" was searched on two databases i) Pubmed and 2) www.lens.org.

PubMed database having more than 3 million citations and abstracts of biomedical literature was used. A search query of liposomes on PubMed in the abstract yielded a dataset of 6,292 research articles. Further, this dataset was filtered with the "University" in the field "affiliation". This search query resulted in 4,012 research articles.

The Lens provides more than 200 million scholarly records, compiled and harmonised from Microsoft Academic, PubMed, and Crossref, enhanced with OpenAlex and UnPaywall open access information, CORE full text, and links to ORCID. This database has a wider coverage of scholarly publications. Therefore, a similar search was conducted on lens.org. The search query of Liposome in title results in 37,592 documents which include (30,732) Journal Article, (3,448) Unknown (1,155) Book Chapter, (744) Dissertation, (701) Component, (311) Conference Proceedings Article, (135) Preprint, (133) Book, (67) Dataset, (42) Review, (41) Other, (38) Reference Entry, (19) Report, (10) Conference Proceedings, (5) Letter, (4)Standard,(3)Clinical Trial, (3)Editorial and (1)News.

Table 1. Search query for research articles

S.No.	Query		Items found
1.	Search (liposome[Title]) and university[Affiliation]	PubMed	4,012
2.	Search liposome[Title]	PubMed	6,292
3.	Search (liposome[Title])	lens.org	37,692

3. RESULTS & DISCUSSION

The patenting trend in liposomes (Fig. 1) has shown tremendous growth since 1995 and it continues to grow to till date. Academic/ research institutes as well as industries are focused on liposomes as potential drug delivery systems for various therapeutic category medicines. Fig. 1 shows the year-wise filing, publication, and grant of patents. The significant growth in patent documents began from the year 2000 onwards. This can also be attributed to the fact the TRIPS was implemented in 1995 by the World Trade Organisation for its member countries with specific terms and conditions for developed, developing, and least developed nations.

The legal status of these patent documents shows that the active patents and the patent-pending (under examination) accumulate to around 26000 patent documents. Thus, out of 53,000 patent documents, around 14000 documents have been discontinued and are inactive (due to non-payment of annuity fee or maintenance fee). This contributes to more than 20 % of the entire dataset which means that the patent applications were filed, and published, and maybe a few percent got granted but later due to some reasons were discontinued. The major reason could be a scarcity of money to keep these patent documents active as patent applications or as granted patents. Also, the conversion rate of patented inventions to commercial products is very low. This is an extremely important point. The patents were filed but the commercial aspect could not get triggered or these documents were filed just as a part of research activity. Filing patent documents incurs costs on the research. Efforts are going on in various directions. Building research parks, incubation cells or centers in universities, and academic institutes, special funding schemes for researchers to explore the commercial potential of their laboratory inventions, etc are many such initiatives. However, one advantage of such filing activity is that the researchers disclose their inventions to the scientific community and the other researchers may use these publicly available documents for improving their research.

An important aspect of this patent dataset was the top assignees as shown in Table 2. The top assignee is the University of California with 958 patent documents, followed by the University of Texas with 714 patent documents. The top 10 applicants also included industries like Liposome Co. Inc (443), Alza Corp (329), Yissum Res Dev Co (263), etc. The patenting activity by industries is a positive sign which reflects the commercialisation potential of Liposomes. However, the 443 dataset of

Liposome Co. Inc. was further analysed and it was observed that at present out of 443, 356 patent documents have expired or discontinued. Further, it is important to mention here that the filing pattern of Liposome Co. Inc. was not the same as that of the complete dataset. The patenting activity was seen between 1985 to 2004, thereafter negligible patents have been filed.

Table 2. Top applicants with number of patent documents number

S. No.	Applicant name	Number of patent documents
1.	University of California	958
2.	University of Texas	714
3.	Liposomes Co Inc	443
4.	Massachusetts Institute of Technology	387
5.	Alza Corp	329
6.	Yissum Res Dev Co	263
7.	Transdermal Biotechnology	245
8.	Glazosmithkline biologicals	239
9.	US Health	227
10.	Centre Nat Rech Scient	220

The second highest filer industry is Alza Corp. The patenting trend of this firm is similar to Liposome Co. Inc. At present, it has 108 patents (out of 329) which are active and are at different stages. Like Liposome Co. Inc., Alza filing also reduced significantly since 2004. However, it is interesting to mention that the first USFDA-approved product, Doxil® with improved pharmacokinetics was an Alza Corporation product.

The Patent datasets of the University of California and the University of Texas were also further analysed. The University of California has 958 patent documents that are active as patents or under examination applications. The year-wise patenting activity of the University of California replicates the pattern of the complete dataset. This leads us to conclude that this university is still actively pursuing research in the field of liposome but the share of year-wise filing of patents by industries in the parent dataset is reducing. Thus, the majority of research is taking place in universities. A similar pattern was seen in the University of Texas patenting activity.

Another important aspect of the parent patent dataset is the field of research w.r.t. liposomes. Figure 2 provides a heat map of the top Cooperative Patent Classification (CPC) of this dataset provides the key research field. There are more than 12,500 patents with a CPC classification of A61P35/00 which relates to Antineoplastic agents. This reflects that these many patents are the outcome of research wherein liposomes and antineoplastic agents are explored. Another interesting CPC classification with more than 3500 patent documents includes the A61K38/00 which comprises Medicinal preparations containing peptides and beta-lactam rings. A61K31/00 includes cyclic dipeptides e.g. piperazine-2,5-diones, A61K31/00 relates to ergot alkaloids of the cyclic peptide type. The CPC classification A61K45/06 with more than 5,000 patent documents addresses mixtures of active ingredients, e.g. antiphlogistics and cardiac. These are the agents of herbal origin having cardiotonic activity. The CPC classification A61K48/00 refers to Medicinal preparations containing genetic material which is inserted into cells of the living body to treat genetic diseases Gene therapy. This means that around 3000 patents are related to the delivery of gene/ genetic material using liposomes. A61K9/0019 corresponds to injectable compositions and it has more than 4000 patent documents. However, this analysis shows that patents are being filed where research on liposomes for peptide, antineoplastic agents (anti-cancer), anti-viral, anti-microbial, antibacterial, anti-infective, cardiovascular drugs, nervous system drugs, dermatological drugs, anti-inflammatory drugs, Drugs for specific purposes and against vector-borne diseases have been done.

There is only one class A61K9/1277 which deals with the process of preparing. A further insight into this classification patent dataset of 3,845 patents showed very interesting results. The important point is the top 10 applicants of this subset include 10 industrial firms. The patents of this subset are like:

US 8354064 B2 titled Apparatus for producing liposomes and method of producing liposomes by Terumo Kabushiki Kaisha US 11497715 B2 Methods and devices for preparation of lipid nanoparticles by Cureport Inc HR P20221048 T1 Small Liposomes for Delivery of Immunogen-Encoding Rna GlaxoSmithKline Biologicals Sa WO 2022/234050 A1 Methods for Producing Nanoparticle Dispersions by Leon Nanodrugs Gmbh These patents of CPC classification code A61K9/1277 are a few representative patents that draw attention to the criticality of the process for preparing liposomes.

The country-wise distribution of the parent patent dataset shows the maximum number of patent documents are from the United States of America followed by WIPO applications, European patents, China, then Japan, Canada, and Australia. Two inferences can be drawn from this information a) maximum research activity is taking place in this order of countries and b) the applicants/ inventors envisage these countries as the potential market for their inventions. Both these inferences have certain presumptions. However, the huge number of patent documents filed in the USA and European countries can be attributed to the above points. These countries spend substantial money on R&D projects and it has wherewithal to commercialise such products which can be reviewed by FDA/EMA and their population can afford such products.

Both the research article datasets resulted in a substantially different number of documents; however, the common finding in both datasets was the contribution of universities. The published dataset had 63% of the research papers with authors having affiliation with the University. The top institutions of the lens.org dataset

included only universities. Table 3 shows the grid of top institutes of 37,692 datasets. Osaka University, Utrecht University, Kyoto University, University of Tokyo, and University of California are among the top universities publishing research articles in the field of liposomes. Further a deep analysis of the specific fields of publications, maximum research papers appear to be related to basic research areas. However, there is a large number of documents that discuss the issues related to the commercial development of Liposomes, but the majority of them are basic research articles as shown in Fig. 3.

The patent document and the research documents search and analysis results provide overlapping data. However, patent documents have a considerable proportion of industrial research in the field of liposomes but the majority of the documents are the outcome of basic research work. The commercialisation of any product needs the active involvement of industry. However, the driving factors of industry and academic research are very different. It is well understood that basic research is the precursor of the commercialisation of a product. However, a field like Liposome which is more than 60 years old and still there are around 17 commercial products calls for a need for serious brainstorming in the scientific community. The key issues must be identified and the research orientation should be amended accordingly.

Table 3. Top institutions published - research articles on liposomes

S. No.	Institutions	Published research articles on liposomes
1.	Osaka University	395
2.	Utrecht university	320
3.	Kyoto University	293
4.	University of Tokyo	279
5.	University of California	266
6.	Shenyang Pharmaceuticals	265
7.	Sichuan University	250
8.	Centre National De La	227
9.	National Institutes of Health	226
10.	French Institute of Health	208
11.	China Pharmaceutical	203
12.	Peking University	201
13.	Hebrew University of Jerusulam	196
14.	Chinese Academy of Science	194
15.	Russian Academy of Science	181

4. CHALLENGES IN COMMERCIALISATION AND POTENTIAL AREAS OF RESEARCH PROJECTS

Extensive research on liposomes has resulted in tangible outcomes with several formulations being commercialised after thorough review from regulatory bodies[4]. Table 4 provides the list of liposomal products available commercially. A maximum number of patents were observed with doxorubicin which is the active ingredient of the first Liposomal drug delivery product approved by USDFA in 1995. It was the first liposomal product. After extensive research and efforts over 14 years, this product was made commercially available[5]. In addition, there are more than 100 clinical trials under progress wherein the Liposomal Formulations are under examination[6]. Clinical trial permissions are obtained after the technology has been successfully developed at the commercial level. A higher number of under-progress clinical trials is a positive indication for this article. With more than 100 clinical trials and 17 commercially approved products, the field of liposomes still offers a huge potential for more products[7]. The key factor is the industry involvement in developing more and more liposomal formulations at commercial level. Extensive research on liposomes is evident with the number of patent documents and research articles published worldwide[8].

The translation of the research to commercial use needs the development and validation of technology, instruments, protocols, processes, stability, in-process quality control, etc. Once these stages are completed, then only clinical trial permission is sought from the regulatory body. A clinical trial is the most unpredictable stage which is extremely cost-intensive and time consuming with a very low probability of success[9]. This is another major factor that deters the industry to precede high-end technology products like Liposomes.

Establishing the need and its economic viability for the development of Liposomes as a drug delivery system is the first step which should be addressed carefully before proceeding research project[10]. In general, liposomes have been used to protect in vivo degradation of drugs, modify drug release, biodistribution, or target drugs to the site of disease[11,12]. Research on Liposomes is easier and practically feasible at the laboratory level but the key factors like cost-benefit analysis, the industrial development process for the preparation of liposomes, and instrumentation requirements both at the laboratory level and industry level are not addressed at the time of initiating a project/research work[13]. Further, the need for the development of liposomes must be explicitly addressed w.r.t. biopharmaceutical or pharmaceutical parameters.

Manufacturing of liposomes at laboratory Level as well as industrial level is a challenging field. Several methods of preparation of liposomes are available in literature. The preparation of liposomes at the laboratory level with a batch size in mg results in the desired liposomes[14]. The instrumentation required for such a small-scale production is very basic and does not need special instruments. Further, the laboratory-level product is a controlled process. The process parameters can be easily controlled without the fear of losses as compared to industrial-scale production. Laboratory-level development facilitates the experimentation with chemicals and process parameters to achieve

the perfect liposomes. This is not practically possible in industrial-scale production. The control of critical process parameters at the industrial level requires research & development for industrial-scale production. Therefore, it is important to widen the scope of work for any project from laboratory development to industrial development at the initiation of a project.

The physicochemical properties of liposomes make them a unique drug delivery carrier system. Due to the lipid base of liposomes, the degradation profile including microbiological, physical, and chemical, pharmaceutical stability, including the integrity of the liposomes in the drug product must be performed thoroughly. Liposomes can be designed by researchers to achieve the desired properties. A thorough characterisation of liposomes during their development stages strengthens the potential for commercialisation. Therefore, this aspect of project proposals must be performed very sincerely and only formulations with more than a 95 % confidence level should proceed to the pre-clinical evaluation stage.

The preclinical evaluation of liposomes is a critical characterisation parameter. Pharmacokinetics, pharmacodynamics, proof of concept studies especially the delivery of drug at the targeted site, animal model development for efficacy evaluation, cell line studies, etc are some important studies that are performed under preclinical evaluation of liposomes[15]. Preclinical studies should include proper animal models or the use of more than one model could help scientists predict clinical results more confidently. Dedicated research projects for harmonisation of research must be encouraged.

5. CONCLUSION

Liposome has been an interesting field for researchers wherein thousands of scientists, and research fellows have contributed and created a pool of information with thousands of patent documents and research publications over the last 60 years[16]. There are around 17 commercially available products. The patent filing trends of liposomes explicitly bring out that the research is under progress. A major contribution of the universities in filing patents and publications is a positive indication. However, the technology map of patents highlights the need to reorient the research projects in line with the needs of industrial research. The research projects need to be strategically planned with a focus on industrial development. Challenges of developing liposome formulations like characterisation, technology development, validation, industrial manufacturing, storage, stability, pre-clinical evaluation, etc must be the thrust areas of research for liposomal drug delivery systems.

Table. 4 Clinically available liposome-based products

S. No.		Active ingredient	Marketed by	Therapeutic category	Number of patents
1.	Doxil®	Doxorubicin	Sequus Pharmaceutical, USA	Anti-Cancer	2,200
2.	DaunoXome®,	Daunorubicin	NeXstar Pharmaceuticals USA	Anti-Cancer	955
3.	Depocyt®	Cytarabine	SkyPharma Inc.	Anti-Cancer	676
4.	Myocet®	Cyclophosphamide	Elan Pharmaceuticals	Anti-Cancer	1076
5.	Mepact®	Mifamurtide	Takeda Pharmaceutical	Anti-Cancer	4
6.	Marqibo®	Vincristine	Talon Therapeutics.	Anti-Cancer	1139
7.	Onivyde™ by	irinotecan	Merrimack Pharmaceuticals	Anti-Cancer	1025
8.	Abelcet®	amphotericin B	Leadiant Biosciences, Inc.	Anti-Fungal	418
9.	Amphotec®	AmB cholesteryl sulphate complex	Ben Venue Laboratories Inc., Bedford, OH, USA	Anti-Fungal	418
10.	Ambisome®	amphotericin B	Astellas Pharma USA	Anti-Fungal	418
11.	Visudyne®	Verteporfin	Novartis AG, Switzerland	Photodynamic Therapy	131
12.	Exparel®	bupivacaine	Pacira Pharmaceuticals	Pain Management	309
13.	Inflexal® V	inactivated, virosomal-adjuvanted influenza vaccine	Crucell, Berna Biotech	Viral Infections	1314
14.	DepoDur™	morphine sulphate	SkyePharma, San Diego, CA	Pain Management	205
15.	Epaxal®.	virosome-adjuvanted vaccine for hepatitis A	Crucell, Berna Biotech	Viral Infections	1636

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He has contributed by guiding data collection and structuring this article.