

**ALTERNATIVES TO INTELLECTUAL PROPERTY
RIGHTS BASED PHARMA INNOVATION MODEL:
A STUDY ON OPEN SOURCE DRUG
DEVELOPMENT**

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This is to certify that this thesis entitled “**Alternatives to Intellectual Property Rights based Pharma Innovation Model: A Study on Open Source Drug Development**” submitted by Mr. Narendran T. for the degree of Doctor of Philosophy, is, to the best of my knowledge, the record of bonafide research carried out under my guidance and supervision from 1st February, 2011 at the Inter University Centre for IPR Studies, Cochin University of Science and Technology. This thesis or any part thereof has not been submitted elsewhere for any other degree.

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This is to certify that the important research findings included in the thesis entitled “**Alternatives to Intellectual Property Rights based Pharma Innovation Model: A Study on Open Source Drug Development**” have been presented in a research seminar at the Inter University Centre for IPR Studies, Cochin University of Science and Technology on 30th March 2017 and all the relevant corrections and modifications suggested have been incorporated in the thesis.

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Declaration

I declare that the thesis entitled “**Alternatives to Intellectual Property Rights based Pharma Innovation Model: A Study on Open Source Drug Development**” for the award of the degree of Doctor of Philosophy is the record of bonafide research carried out by me under the guidance and supervision of **Prof. (Dr.) N. S. Gopalakrishnan**, Honorary Professor, Inter University Centre for IPR Studies, CUSAT. I further declare that this work has not previously formed the basis of the award of any degree, diploma, associate-ship or any other title or recognition.

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PREFACE

Open source is a fascinating concept. In a materialistic world, it is indeed a surprising fact that people would volunteer to collaborate and create together without any direct economic returns. It depicts the altruistic virtue innate in all human beings. It also characterizes a new economic model that is based on social sharing and exchange. The emergence of such a model can significantly transform the way in which research and development happens. This also makes it feasible to organize production even outside the constraints of industry. It signals the possibility of liberating research from the limitations of market based production and thus in turn facilitating development of socially relevant innovations. Conversely, the greatest challenge raised by this model relates to the management and exploitation of intellectual assets generated therein for economic gains. This and the associated array of complex issues triggered an attraction towards this topic as my doctoral thesis.

This is the moment to express my profound gratitude to Prof. (Dr). N. S. Gopalakrishnan, my supervising guide whose timely interventions provoked, challenged and sharpened my thought process, often leading my research to new directions. His hectic schedule never influenced his kindness to discuss with me every aspect of my thesis in great detail. With great honour, I feel indebted to him for all the efforts he has taken in shaping my thesis.

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ABBREVIATIONS

| | |
|-------------------------------------|---|
| AFL | Academic Free License |
| AIDS | Acquired Immuno -Deficiency Syndrome |
| AIPLA QJ | American Intellectual Property Law Association Quarterly Journal |
| AT&T | American Telephone & Telegraph Company |
| BMJ | <i>British Medical Journal</i> |
| BSD | Berkeley Software Distribution |
| BSDI | Berkeley Software Design Incorporated |
| BTL | Bell Telephone Laboratories |
| Cardozo Arts & Ent LJ | <i>Cardozo Arts & Entertainment</i> Law Journal |
| CEWG | Consultative Expert Working Group on Research and Development |
| Co. | Company |
| CRDD | Computational Resources for Drug Discovery |
| CSIR | Council of Scientific & Industrial Research |
| DEC | Digital Equipment Corporation |
| DHDPS | Dihydrodipicolinate Synthase |
| DNDi | Drugs for Neglected Diseases Initiative |
| Duke L. J. | Duke Law Journal |
| EULA | End User License Agreement |
| FDA | Food and Drug Administration |
| Fed. Cir. | <i>Federal Circuit</i> |
| Fla. St. UL Rev. | Florida State University Law Review |
| Fordham Intell. Prop Media & Ent LJ | The <i>Fordham Intellectual Property, Media and Entertainment</i> Law Journal |
| GDP | Gross domestic product |
| GIP | Green Intellectual Property Project |
| GNU | GNU's Not Unix |

| | |
|---------------------------|---|
| GPL | General Public License |
| GSK | GlaxoSmithKline |
| HIV | Human Immunodeficiency virus |
| Hofstra L Rev | <i>Hofstra Law Review</i> |
| HP | Hewlett-Packard |
| IBM | International Business Machines Corporation |
| IEEE Ann Hist Comp | IEEE Annals of the History of Computing |
| IEEE | Institute of Electrical and Electronics Engineers |
| iOWH | Institute for One World Health |
| IP | Intellectual Property |
| IPR | Intellectual Property Rights |
| J Int Economic Law | <i>Journal of International Economic Law</i> |
| J Law Econ Organ | <i>Journal of Law, Economics & Organization</i> |
| MDR-TB | Multi-drug-resistant tuberculosis |
| Minn JL Sci & Tech | <i>Minnesota Journal of Law, Science & Technology</i> |
| MIS | Management Information Systems |
| MIT | Massachusetts Institute of Technology |
| MMV | Medicines for Malaria Venture |
| MPP | Medicines Patent Pool |
| MSD | Merck Sharp & Dohme |
| <u>Mur. UEJL</u> | Murdoch University Electronic Journal of Law |
| Nat Rev Drug Discov | Nature Reviews <i>Drug Discovery</i> |
| NCATS | National Center for Advancing Translational Sciences |
| NGO | Non-Governmental Organization |
| NIH | National Institute of Health |
| NTD | Neglected Tropical Diseases |
| NYU J Intell Prop & Ent L | <i>New York University Journal of Intellectual Property and Entertainment Law</i> |
| NYU Press | New York University Press |

| | |
|---------------------|--|
| OIDD | Open Innovation Drug Discovery |
| OIP | Open Innovation Platform |
| OSDD | Open Source Drug Discovery |
| OSI | Open source Initiative |
| OSM | Open Source Malaria |
| OSS` | Open Source Software |
| Oxf Rev Econ Policy | <i>Oxford Review of Economic Policy</i> |
| PACT | Project For the Advancement of Coding Techniques |
| PhRMA | The Pharmaceutical Research and Manufacturers of America |
| PLoS Med | <i>PLOS Medicine</i> |
| PLoS Negl Trop Dis | PLOS Neglected Tropical Diseases |
| PLOS | Public Library of Science |
| R & D | Research and Development |
| RAND Corp. | Research And Development Corporation |
| SNP | Single Nucleotide Polymorphism |
| TB | Tuberculosis |
| TDR | Special Programme for Research and Training in Tropical Diseases |
| TIPR | Transferable Intellectual property rights |
| TMRC | Tech Model Railroad Club |
| TRIPS | The Agreement on Trade-Related Aspects of Intellectual Property Rights |
| U. Chi. L. Rev. | <i>University of Chicago Law Review</i> |
| UMKC Law Review | University of Missouri-Kansas City School of Law Review |
| US | United States |
| WHO | World Health Organization |
| WIPO | World Intellectual Property Organization |
| Yale L J | Yale Law Journal |

Chapter 1

Introduction

The evolution and spread of Internet has led to a technological context where it is possible for individuals around the world to collaborate and create irrespective of their place, language and time zone. This has radically changed the way in which information and knowledge production happens. Marxian criticism on capitalism is that bourgeoisie who owns the means of production uses it as an instrument to exploit the labor and accumulate capital¹. But the information revolution has led to a situation where there is no more concentration of ownership over the means of production for information resources. The means of production has become so accessible, that it is no more the ownership over machines that determine the capitalist's role in production process. This has resulted in the information production being possible even outside the constraints of industry and led to the development of a new production model based on voluntary participation in community endeavors. The social production of modern times has thus emerged out of 'free labour' which is organized to collaborate and create in a digitally connected environment. This led to an explosion of creativity that surpasses all major achievements that mankind had witnessed in last few decades². The GNU, Linux and Wikipedia are all examples of the exemplarily creative works that were developed through social organization of free labour. The further advancement of technology has resulted in the social production and exchange system becoming more and more inexpensive to operate. This democratized the innovation process and has brought in a socio-cultural shift in industrial production.

The emergence of social sharing and exchange as the most efficient mode of production is indeed a surprising fact. A powerful criticism about capitalist production

¹ Karl Marx and F. Engels, *The Communist Manifesto* (first published 1848, Progress 1967) 16

² Eric E Johnson, 'Intellectual property and the incentive fallacy' (2011) 39 Fla. St. UL Rev. 623, 625

model is that it has negated human relationship and has replaced it with a relationship between man and machines. Thus when an economy based on social sharing and exchange emerges as a production model, it would indeed be interesting to see if it makes any material change in the social relationship of modern times. If not, then it warrants a serious consideration of the philosophical direction in which these new models of social production are being taken. As an economic phenomenon, social production has now become more important than ever before. This has brought together 'capital' and 'social labor' which were two ever opposing concepts. 'Capital' has always been represented as that force which has tamed 'wage labour' and used it as an instrument for wealth generation. The rapid growth of capital resulted in widening the divide between the worker and the capitalist. It also led to the increase in the power of capital over labour and resulted in greater dependence of labour over capital³. This led to an economic condition where the capital enjoys the ability to determine how the labour is utilized and for what purpose. As the primary concern of capital is wealth generation, the allocation of labour becomes limited only to those ventures that have the potential to generate profit. This resulted in a dearth of creative efforts to address social necessities of human life. It also impaired the laborer's ability to create in accordance with his choice. The emergence of social production models is as an alternative to the market based production model controlled by the capital. It has to be seen as a laborers' revolt against the strangulation of their creative freedom. It is only that the growth of technology further eased the process and made the alternative models possible. In the course of time, these models have emerged as a challenge for the companies operating in a traditional centralized market based framework. But this does not mean that production has become less capital intensive. In reality this has opened up new possibilities to make the economic production more efficient than corporate model. This has necessitated the adaption of capitalist production process to these new challenges and to look for a model that can capitalize

³ Karl Marx and Friedrich Engels, *Wage-labor and capital* (first published 1849, International publishers 1969) 208.

on social production. But it requires many changes in the organizational culture followed by industries which includes replacing the control based management structure with freedom based principles.

Even though open source software is not the only form of social production that has emerged in the recent decades, it has spread to many other realms outside software industry as an ideological construct capable of radically transforming the innovation process. Historically, the origin of open source is associated with a longer tradition in which freedom to work on technology was well accepted. In the early days of computing history, software was considered as the product of collective labor which was freely shared among users who were free to modify and improve it, and share it again. In fact, there existed a cultural and legal perception that software is a pre-competitive tool⁴. This is also associated with the constraints that programmers faced as computing is an emerging technology. This had necessitated collaboration across industries and universities to develop computer programs for their use. The social sharing of source code and freedom of users to modify it was an integral part of the programming culture. But by the late 1960's and with the beginning of 1970's, commercial sale of software started⁵. As a result, the source code which was traditionally treated as a public domain resource open for the users to adapt, modify and improve, started to be treated as a proprietary product. This resulted in non-revealing of source code by commercial vendors as a precaution against unauthorized duplication and modification. Soon proprietary software became a usual thing which dominated the computer industry. This took away the programmer's freedom to modify the software to suit his needs and share it to others. Open source movement gained momentum as a creators' response against the non-revelation of source code by proprietary vendors. By the 1980's, different groups emerged who believed in software freedom and their main focus was on

⁴ Steve Weber, *The success of open source* (Harvard University Press 2004) 25.

⁵ Emerson W Pugh, 'Origins of software bundling' (2002) 24(1) IEEE Ann Hist Comp 57, 58.

accessibility to source code. Some groups attached ethical considerations to software with open codes, while others viewed this only as a convenient practice. Open source too, worked on intellectual property framework, but making use of licensing system distribute right to users in such a way to improve access and facilitate sharing of improvements. With the growth of proprietary software business, open source also grown and resulted in proliferation of different groups with similar but not identical motivations. This was mainly because the considerations of different groups varied from economic utilization, open access, etc. to values and ethics. This resulted in publication and adoption of different licenses by different communities. An in-depth analysis of these licenses reveals the philosophical confusion surrounding them. There exists very limited conceptual clarity as to what exactly is 'open source', even though few basic features could be identified.

The uniqueness of open source model is in facilitating a distinctive use of property to build an environment that is more conducive to collaborative production. The efficiency of open source production model is in coordinating collaborative creativity by guaranteeing research freedom. There exists a strong view that open source is antithetical to intellectual property and it is a viable alternative to the contemporary model. Proponents like Richard Stallman⁶ has extensively written on free software movement and tried to theorize it as a philosophy antithetical to intellectual property ideals. Writers like Steven Levy⁷, Michele Boldrin⁸, Stephen Kinsella⁹, Mikko Valimaki¹⁰ etc. have tried to examine the concept of open source and advocated for it as an alternative to intellectual property. This resulted in open

⁶ Richard Stallman, *Free software, free society: Selected essays of Richard M. Stallman* (Free Software Foundation Inc 2002).

⁷ Steven Levy, *Hackers - Heros of the Computer Revolution* (Boston Doubleday Dell Publishing Group Inc 1984).

⁸ M. Boldrin and D. K. Levine, *Against Intellectual Monopoly* (Cambridge University Press 2008).

⁹ N Stephen Kinsella, *Against Intellectual Property* (Ludwing Von Mises University 2008).

¹⁰ Mikko Valimaki, *The Rise of Open Source Licensing - A Challenge to the Use of Intellectual Property in the Software Industry* (Turre Publishing 2005).

source being identified as a philosophy which offers a workable solution that resolves many challenges intellectual property law has posed in terms of access and creativity management. This led to adoption of 'open Source' production model into newer realms of technology. Open source model of collaborative research attempted in chemistry, biology, communication technology, robotics etc. are all examples of this trend¹¹. Open source model relies on the intellectual property based licensing system to create a binding legal relationship between the creator, project owner and the user. Its distinctiveness is mainly in the way in which the licensing system is used to promote access to collaborative creation and thereby opening up the possibility for perpetual improvement. But at the same time, open source is a thriving business model which has got wider acceptance in information technology sector¹². A deeper analysis of open source licensing reveals the use of property rights to establish control ownership over the community creation and thereby regulating the creative process by versioning, branding and releasing the community creation. This in essence opens up the possibility to build business models and thereby commercially benefit from the community creation. But at the same time open source is a workable model to organize social labor to serve community goals, particularly in contexts where contemporary intellectual property model has tied down creativity to market based production. The projection of open source as a probable alternative to intellectual property raises many critical questions as to the philosophical confusions surrounding this model and its suitability to other realms of technology. The origin of open source was indeed a response to the restrictive approach set by intellectual property protection. But how far open source is successful in liberating creativity from market control is a serious concern that needs to be probed. Thus the nature of property in open source and its social organization

¹¹ The amenability of open source research model to different fields of technology are being explored. The details of Open source chemistry can be accessed at <<http://www.openchemistry.org/>> (accessed 21 March 2016). See for further details. <<https://www.nature.com/nature/journal/v431/n7008/full/431491b.html>> (accessed 21 March 2016).

¹² Steve Weber, *The success of open source* (Harvard University Press 2004) 11

need to be critically analyzed to find out how far open source being a property based model can emerge as an alternative to contemporary intellectual property model.

Open source drug development is being attempted as an alternative to address the failure of intellectual property led pharmaceutical models in drug discovery for neglected diseases. The contemporary model of pharmaceutical research has resulted in the focus of drug development being too dependent on the existence of a viable market. Investors in health R&D perceive the market exclusivity granted by intellectual property rights as an opportunity to recoup their investment. So far intellectual property rights have been successful in incentivizing investment into pharma sector. But a major drawback of intellectual property rights system is identified as its failure to trigger innovations for medical needs of third world countries which cannot offer a viable market for pharma companies¹³. Apart from this, the industry is also facing an innovation crisis which is characterized by a drop in productivity¹⁴. Absorption of external innovations is suggested as a strategic option to overcome this challenge¹⁵. It is now an accepted fact that success cannot be grounded solely on internal innovations. Even now a significant percentage of the late stage pipeline of big pharmaceutical companies consists of potential drug candidates acquired from external sources¹⁶. Open collaborative drug development is thus being taken up as an alternative model that can efficiently reorganize pharmaceutical research. Open source is one model of implementing open

¹³ WHO Consultative Expert Working Group on Research and Development: Financing and Coordination, *Research and Development to Meet Health Needs in Developing Countries – Strengthening Global Financing and Coordination* (WHO 2012) 56

¹⁴ Fabio Pammolli, Laura Magazzini, and Massimo Riccaboni, 'The productivity crisis in pharmaceutical R&D' (2011) 10 (6) *Nat Rev Drug Discov* 428, 435.

¹⁵ Deloitte Center for Health Solutions, 'Executing an Open Innovation Model: Cooperation is Key to Competition for Biopharmaceutical Companies' (Deloitte 2015).

¹⁶ D. W. Light and J. R. Lexchin, 'Pharmaceutical Research and Development : What do we get for all that money' (2012) 345 *BMJ* <<http://www.bmj.com/content/345/bmj.e4348.long>> (accessed 3 March 2016).

collaborative drug development¹⁷. Eli Lilly, Astra Zeneca, GlaxoSmithKline and Pfizer are some of the pharmaceutical companies that have attempted open collaborative research. It must be noted that none of these examples completely relinquish proprietary ownership. Instead they perceive proprietary ownership as a tool to engage with collaborators. Thus it is clearly evident that most of the pharma funded models of collaborative drug development relies on patenting to ensure effective control over the product development process. This shows the confidence that the industry has over intellectual property based business models. The impact of the use of open source model for innovation in drug development and reliance on patent for production and distribution of the new products also needs to be probed to find out whether the social benefits that open source generally offers could be achieved.

Apart from the industry, public funded organizations and NGOs are also piloting open collaborative research. Open Source Malaria¹⁸ and CSIR's OSDD¹⁹ are examples of attempts to implement open source approach in drug development. These collaborative models accelerate health R&D and expect to make themselves sustainable through innovative management of evolving intellectual property. Some collaborations put their innovations in public domain while most others use intellectual property protection. Those who use property rights protection, view it as an important tool to control 'product development process' and to negotiate with manufacturing and distributing partners on price and accessibility of drugs²⁰. Further intellectual property right is also relied on to maintain open access and foster additional and follow on research. It would be interesting to find out how these

¹⁷ Deloitte Center for Health Solutions, 'Executing an Open Innovation Model: Cooperation is Key to Competition for Biopharmaceutical Companies' (Deloitte 2015).

¹⁸ Available at < <http://opensource malaria.org/> > (accessed 12 January 2017).

¹⁹ Available at < <http://www.osdd.net/> > (accessed 12 January 2017).

²⁰ James M Shaeffer and Sarah MacDonald, 'Innovation: Open Source and Nonprofit Models in Drug Discovery' in Rathnam Chaguturu (eds), *Collaborative Innovation in Drug Discovery* (Wiley 2014) 21.

projects attract volunteers, what would be their motivations, how the collaborative research is organized and how the intellectual property is managed. It is ideal that these puzzles are resolved through an empirical study. Thus an empirical study is done on CSIR's OSDD project to find out answers for at least some of these questions. The OSDD project was chosen for study as it is hosted in India and thus was logistically easier to do.

Open source could be a possible solution to crowd source research in areas where the current model has failed due to its excessive reliance on market considerations. The failure of present model is primarily because the innovation incentive is directly linked to market exclusivity and drug pricing. Open collaborative drug discovery could be considered as an option to overcome this crisis. But implementing an open source model will be a challenging exercise considering the complexities involved in drug development²¹. The major success of open source has been in software development. Both the drug discovery research and open source software development are decentralized production models with partitioning and distribution of tasks. But there exist significant differences between the drug discovery research and software development. The amenability of drug development research to open source methodology is a major challenge which needs to be probed. Moreover, the adoption of open source production model in pharmaceuticals generates many complex issues in terms of organization, implementation of collaborative production, delivery and intellectual property management. Further drug development research requires some advanced resources like lab facilities, databases, computational tools, chemical analysis tools etc. It also requires advanced scientific knowledge incomparable with computing time of hobbyists. Further drug development is subject to stringent regulations. Thus clinical trials and regulatory approval is mandatory before the product is made available to

²¹ Stephen M Maurer, 'Open source drug discovery: finding a niche (or maybe several)' (2007) 76 UMKC L Rev 405

public. There may also arise many challenges in terms of managing the intellectual assets created through collaborative research.

The success of open source model in software industry was the result of efficient use of property to develop viable business models. Thus engaging with the collaborators in open source environment enables the companies to build their business models thereby exploring the possibilities for revenue generation. But control ownership over community research will be a pre-requisite to build business models. The presence of strong property rights will be required to facilitate this. The industry promoted models were relying on patent rights as it closely aligns with the pharma business model. However, some other models have openly relinquished proprietary rights and vowed to put the research results in public domain. Pharmaceuticals is one sector that have stringent market regulations. Thus the final stage drug development and securing of regulatory approval requires active participation from industry. This can be ensured only by providing expressive incentives in the open source framework. The open source approach is possible in pharmaceutical research if efficiently organized and supplemented by a workable business model. But integration of business models shall not be done at the cost of sacrificing the public health objectives. Thus it is important to examine whether the use of property in open source drug development models is adequate to build viable business models. Such a study will help in the identification of the limitations in the existing open source models on pharmaceuticals and can contribute towards the designing of a workable model of open collaborative drug development.

Chapter 2

The Philosophy of Open Source

'Open source' simply means that the source code of a computer program is openly available for use without many restrictions. This terminology is commonly used to signify a production model for software development. As a production methodology, open source is characterized by numerous volunteers contributing to the process of software development in a systematic manner and the resultant software's source code being kept open. Most of the open source software are free of cost, that way easily accessible and even modifiable to suit personal requirements. The 'accessibility' factor makes the open source software highly popular. This in turn tempts the creative users to contribute towards its improvement which make the software technologically superior than its competitors. In the capitalist mode of production, the creative consumers used to play only a passive role. Open source brought in a significant change in the production process by involving creative users as producers of information resources. This resulted in the spreading of a culture of working together to resolve the common challenges. The popularity of this production model and its success in software industry has inspired its adoption into many other fields of technology. It is also being promoted as capable of making the industrial research more efficient to overcome the challenge of access, that current model of production has created. Industries have started pursuing open source as a workable solution to more efficiently organize research and bring down the development cost by utilizing social labor.

Even though the formalization of the concept of open source happened only in the 1990s, the collaborative software development existed from the very early days of computing. In fact, the nearly 70 years history of computing technology has several instances of collaborative research undertaken at different levels to resolve the common challenges faced by programmers. As a unique production model, open

source is often pointed out as an alternative to intellectual property rights. At the same time 'open source' has often been criticized as lacking a solid theoretical foundation making it purely contextual and inapplicable for areas other than software development. Interestingly, open source works within the intellectual property framework itself and uses its unusual licensing terms to reduce proprietary claims by relinquishing several rights to the users. But there exist significant differences in approach even inside the 'free software' and 'open source' movement itself. In essence its ideological foundation has two distinct views. Supporters of 'free software' perceive it as a social movement¹ while proponents of 'open source' describe it simply as a convenient practice. Needless to say, there is a lack of clarity as to what exactly is free and open source. In order to fully understand the concept of openness, it is very essential to know the context of origin of open collaborative programming. That will probably give a better insight into the theoretical foundation of open source.

2.1 Context of an early cooperation

If open source's focus is on the social organization of software production, its origin is deeply rooted in the constraints on independency in computing. Early generations of computers were primordial and highly complex to handle². The capabilities that modern day computers possess like huge memories, fast processors, reliable and vast storage media and most importantly, connectivity were hardly imaginable in the early days³. It was indeed a very complicated task to make the machine perform a desired task. In the modern computing, software written in popular programming languages take on this job. But during the early years of computing, this was a strenuous task for the programmers as they had to program

1 Richard Stallman, *Free software, free society: Selected essays of Richard M. Stallman* (Free Software Foundation Inc 2002) 57

2 Paul E Ceruzzi, *A history of modern computing* (MIT Press 2003) 48.

3 Steve Weber, *The success of open source* (Harvard University Press 2004) 21.