1. Introduction

A. WHAT IS THE PROBLEM WITH THE CURRENT DRUG DEVELOPMENT PROCESS?

To the benefit of individuals and society, medical innovations and technologies have the ability to lead to better healthcare, improve quality of life, and increase longevity. As stated in the 2009 Pharmaceutical Sector Inquiry, a comprehensive study of the European pharmaceutical sector put together by the European Commission (EC), ‘[i]nnovation in human medicines has enabled patients to benefit from treatments that were unimaginable a few decades ago’.1 In addition to providing a better quality of life, research relied upon by the United States National Institute of Health (NIH) on the economic impact and potential of improved health claims that the decline in mortality rate from 1970 to 2000 translated to approximately an added $3 trillion a year in economic activity.2 However, the cost of healthcare and research and development (R&D) to bring new drugs to market is reportedly ever increasing. The average cost of bringing a new drug to market is US$2.6 billion and the average time to develop a new drug is more than ten years.3 In another

---

study, it was reported that the economic burden to society associated with the treatment of chronic diseases such as heart disease, diabetes, and cancer is estimated at US$1.3 trillion or €700 billion a year. Worldwide, Lindborg, and Aaron L. Schacht, How to Improve R&D Productivity: The Pharmaceutical Industry’s Grand Challenge. NATURE REVIEWS DRUG DISCOVERY, 9(3), 203–214 (2010); Michael Dickson and Jean P. Gagnon, Key Factors in the Rising Cost of New Drug Discovery and Development. NATURE REVIEWS DRUG DISCOVERY, 3(5), 417–429 (2004); Joseph A. DiMasi, Ronald W. Hansen, and Henry G. Grabowski, The Price of Innovation: New Estimates of Drug Development Costs. JOURNAL OF HEALTH ECONOMICS, 22(2), 151–185 (2003). However, there is some debate and conflicting reports over the actual cost of drug development. In Donald W. Light and Rebecca Warburton, Demythologizing the High Costs of Pharmaceutical Research. BIOSOCIETIES, 6(1), 34–50 (2011) it was reported that an unrepresentative sample of drug companies provided unverifiable and exaggerated R&D costs data to the Tufts Center for the Study of Drug Development (Tufts CSDD), which formed the basis of the finding of the excessively high average cost to bring a new drug to market. See also Donald W. Light and Joel R. Lexchin, Pharmaceutical Research and Development: What Do We Get for All That Money? BRITISH MEDICAL JOURNAL, 345 (2012), which argued that the often quoted cost data have been used by industry and academics alike when discussing the various views on the drug development process and explaining industry behavior, such as the need for high profit margins associated with new drugs as a means to recuperate sunk R&D costs and to fund further R&D. Kenneth Kaitin, Professor and Director of the Tufts CSDD, asserts that there is no conflict of interest in the articles he publishes that rely upon the DiMasi and Grabowski data. He asserts Tufts CSDD is a nonprofit academic research center at Tufts University, Boston, Massachusetts, which is funded in part by unrestricted grants from pharmaceutical and biotechnology firms, as well as companies that provide related services (e.g., contract research, consulting, and technology firms).

4 European Commission, Health and Consumers Directorate-General (2014) The 2014 EU Summit on Chronic Diseases Conference Conclusions, Brussels; Giuseppe Garcea and Ashley Dennison, The Economic Burden of Chronic Ill Health. EUROPEAN JOURNAL FOR PERSON CENTERED HEALTHCARE, 3(2), 238–244 (2015). See also The Council for American Medical Innovation (CAMI), Gone Tomorrow: A Call to Promote Medical Innovation, Create Jobs, and Find Cures in America, prepared by the Battelle Technology Partnership Practice, June 10, 2010. The Centre for Disease Control and Prevention also published similar statistics on its website in May 2014 in association with its Chronic Disease and Health Promotion awareness campaign (see http://www.cdc.gov/chronicdisease/overview/).
global spending on pharmaceuticals in 2013 approached US$1 trillion.\(^5\) Although in 2014, the United States Food and Drug Administration approved 41 new drugs (17 of which had fast track status and a further eight drugs were approved under the ‘accelerated approval’ program),\(^6\) in the immediate ten years prior, the number of new drugs approved was approximately the same number of drugs approved in the 1950s.\(^7\) Given the available statistics and metrics on the drug development process (illustrated in Figure 1.1), researchers and the pharmaceutical sector alike have commented that the current drug development model may be too cumbersome and therefore stalling the translation of basic science into pharmaceutical products.\(^8\)


\(^6\) U.S. Food and Drug Administration Center for Drug Evaluation and Research (2015) New Molecular Entity Approvals for 2014 Summary Report. However, it should be noted that fast track status is a designation that accelerates the approval of new drugs which show promise in treating life-threatening medical conditions for which no drug or treatment exists or works well. As such, the increased pace of new drug launches may be reflective of greater efficiency in the approval process as opposed to increased drug discovery and development productivity. Perhaps the encouraging signs of pick-up in new drug approvals, which is anticipated to continue, should be viewed with some cautious optimism.

\(^7\) Micheal Hay, David W. Thomas, John L. Craighead, Celia Economides, and Jesse Rosenthal, Clinical Development Success Rates for Investigational Drugs. NATURE BIOTECHNOLOGY, 32(1) 40–51 (2014); Joseph A. DiMasi, L. Feldman, A. Seckler, and A. Wilson, Trends in Risks Associated with New Drug Development: Success Rates for Investigational Drugs. CLINICAL PHARMACOLOGY AND THERAPEUTICS, 87(3), 272–277 (2010). While there are over 7,000 diseases that affect the human population, only 600 of these diseases have treatments and there are even fewer FDA-approved treatments for rare diseases which affect one in ten Americans.

Those involved in the drug discovery and development process have expressed a serious concern regarding the rising R&D expenditures in the pharmaceutical sector, which can create productivity challenges,\(^9\) cost

\(^9\) Kenneth I. Kaitin, *Deconstructing the Drug Development Process: The New Face of Innovation*, CLINICAL PHARMACOLOGY AND THERAPEUTICS, 87(3), 356–361 (2010), which asserts that the pharmaceutical sector, as currently structured, is unable to deliver enough new products to market to
containment pressures from government\textsuperscript{10} and investors\textsuperscript{11} and an increased demand in industry for a competitive edge in the market to maintain shareholder value, thereby unwittingly promoting an over-protective (as opposed to collaborative) environment within the pharmaceutical sector. Much of the cost associated with drug discovery and development is related to the high risk of failure in translating discoveries into safe and effective products, demonstrating how challenging it is to move a molecule from discovery to commercialization.\textsuperscript{12} Furthermore, it has been reported that on average, only three in ten new products generate revenues equal to or greater than average industry R\&D costs.\textsuperscript{13} Given that industry is the only player in the drug discovery and development process that manufactures and makes products derived from basic research available to the public, it is understandable why industry and investors tend to shy away from investing in early stage research and generate revenues sufficient to sustain its own growth and that major drug developers are critically examining their R\&D practices and considering different R\&D models. To understand why ‘business as usual’ is no longer an option for the pharmaceutical industry, the author cites three main challenges: loss of revenue due to patent expirations, increased demand for proof of concept, and stringent regulatory compliance requirements. Similarly, Clint Gartin, the head of healthcare banking at Morgan Stanley, states: ‘R\&D in pharma and biotech is a very risky exercise. Most projects that are started end in failure’, see Andrew Jack, ‘Pharma Tries to Avoid Falling Off “Patent Cliff”’. \textit{Financial Times} (London, 6 May 2012) (accessible at http://www.ft.com/cms/s/0/572ea510-9452-11e1-bb47-00144feab49a.html#axzz4EmCT0HIL).

\textsuperscript{10} For example, see the initial decision of the National Institute for Health and Clinical Excellence in April 2012 where the UK’s drug rationing body decided not to cover the cost of GSK’s Benlysta, claiming the drug was not cost effective despite there being no alternative treatments for lupus. See article entitled \textit{Benlysta in the UK – Not Covered by the NHS} at http://www.lupus.org.uk/news-events/general/267-benlysta-lupus-drug-not-covered-by-nhs-2
\textsuperscript{12} DiMasi, et al., \textit{supra} note 7 and Hay et al., \textit{supra} note 7.
discoveries in favor of innovations with established indications of viability, such as proof of concept.\textsuperscript{14}

One of the most problematic areas in the drug discovery and development process that has been the subject of much discussion in the literature is the lack of competencies to advance innovations beyond early stage development,\textsuperscript{15} despite large government investments in university R&D, education, equipment, and apparatus in the fields of medicine and pharmaceutical sciences.\textsuperscript{16} University technology transfer offices (TTOs) have generally been criticized for their slow rate of commercialization,\textsuperscript{17} particularly in the field of pharmaceutical sciences because TTOs have limited resources and skills to advance early stage research through to proof of concept. Specifically, the pre-clinical and target validation processes associated with drug discovery and the defining of leads and candidates are complex, lengthy, and unpredictable.\textsuperscript{18} As previously mentioned, the nature of pharmaceutical research is such that very few early stage discoveries actually deliver promising

\textsuperscript{14} European Commission, Enterprise and Industry. The financing of biopharmaceutical product development in Europe: The Framework Contract of Sector Competitiveness Studies – ENTR/06/054 Final Report 2009; Jones and Clifford, supra note 11; Bruce L. Booth, \textit{From the Analyst’s Couch: Valuation with Cash Multiples}. NATURE REVIEWS DRUG DISCOVERY, 4(7), 533–534 (2005). Without better validation tools to allow researchers and industry to identify which candidates have the greatest likelihood of successful development, investors will continue to be risk adverse.


\textsuperscript{18} See for example Declan Butler, \textit{Translational Research: Crossing the Valley of Death}. NATURE NEWS, 453(7197), 840–842 (2008); Cohen, supra note 8; Service, supra note 8.
results due to a high risk of failure compared to other industry sectors. Without the funding or expertise to decide which discoveries have potential, TTOs have a difficult time assessing and marketing early stage research to investors for translation into therapies that may ultimately improve human health. If TTOs fail to attract licensing revenue from investors, basic research projects fail to receive further funding to establish proof of concept to demonstrate commercial and clinical viability.

The European Commission, Directorate General Enterprise and Industry, has reported that venture capitalists (VCs), which have largely driven success in funding medical innovation in the recent past, have effectively stopped making early-stage investments since 2001/2002, citing too many failures and too high a risk/return ratio. The available data and statistics therefore point to a hesitance by VCs to invest in early stage pharmaceutical research, presumably because of their growing intolerance of the unpredictability and risk associated with unproven technologies and discoveries. In other words, the gap between academic research and the evidence of viability demanded by VCs to justify investment has widened. A consequence of industry preference to invest in later-stage technologies is that researchers potentially face increasing difficulty finding funding to translate and develop their early-stage discoveries to provide proof of concept, thereby creating a vicious cycle: investors need proof of concept to invest in the further development of basic research but researchers need investors to invest in early-stage discoveries in order to have the funding to achieve proof of concept.

---

19 European Commission supra, note 14. As stated in the report, venture capital is the most important source of capital for European pharmaceutical companies and drug development, particularly at early stages of development. By participating in early validation of technology, any resulting success may be used to attract other investors.

20 Jones and Clifford., supra note 11, stating that venture capital investors have altered their investment behavior by favoring companies with critical mass or opportunities with existing or near-term products and revenue. See also Arthur Klausner, Mind the (Biomedical Funding) Gap. NATURE BIOTECHNOLOGY, 23(10), 1217–1218 (2005) and Booth, supra note 14, where industry analysts have also reported on the ‘funding gap’ resulting from the increasing reluctance of venture capitalists to invest in early stage discoveries.

From the perspective of those critical of the traditional university technology transfer model, there appears to be a general consensus that this model is an inefficient means to facilitate the translation and commercialization of pharmaceutical discoveries and technologies. Specifically, the traditional technology transfer model fails to provide a mechanism to bridge the gap between early stage academic research and pre-clinical research. Technology transfer consists of the transfer of technological information or knowledge wherein one party gains access to another party’s information for a fee in order to utilize such information. At the risk of stating the obvious, successful technology transfer therefore presupposes the technology is developed to the point where third parties deem it a worthwhile investment (or can reasonably assess the technology’s value) to license the associated intellectual property for commercialization or further R&D purposes. In order to attract investors to license university research, TTOs assert intellectual property rights in university research results in order to have something proprietary to license to interested parties. Without proof of concept, industry partners are unable to assess the risk and rewards to make an informed decision as to whether to make a substantial financial investment in early-stage discoveries. Known as the ‘Valley of Death’, innovations that may be the next ‘blockbuster success’ could potentially fall through the gap and be left undeveloped at the early stages of research because of lack of funding and expertise to bring discoveries to a clinically and commercially investible point to attract industry involvement in translation and commercialization.

---


B. COLLABORATIVE DRUG DISCOVERY AND DEVELOPMENT

Due to the increasing cost of R&D and budgetary and funding challenges in the public research sector, collaborative partnerships between industry and public research organizations, such as universities, hospitals, and other publically funded research institutions may be a pragmatic solution as a means to pool resources and reduce duplication efforts. If collaborative partnerships are to be supported as a means to facilitate the drug discovery and development process, the question then becomes how public research organizations and industry can forge closer ties through partnerships and research collaborations while preserving academic core values and providing industry with the incentive required to justify investment in basic research. It is conceivable to anticipate polarization within academic institutions between those who want to partner with industry as a means to secure research funds required to translate publically funded basic research into pharmaceutical products for the benefit of the public and those who view collaboration with industry as a betrayal of academic objectives and principles. As stated by Louis Berneman, Past President of the Association of University Technology Transfer Officers, university–industry collaborations can restrict or delay academic publication in favor of preserving a company’s proprietary rights. As stated by Eric Campbell, a sociologist at Harvard Medical School in Boston, ‘You should not in any way accept the notion that these giant institutional agreements are without tremendous danger’, see Heidi Ledford, *Drug Buddies*. NATURE, 474(7352), 433–434 (2011) at 434.

---

24 See Moran, *supra* note 15, on bridging the funding gap between the finishing point of research that is funded by academic grants and development of clinical and therapeutic applications funded by the private sector. For example, in June 2011, Pfizer entered into a USD$100 million five-year partnership with eight research institutions in the Boston area to discover and develop new candidate drugs. This came after Pfizer unveiled its plans to cut its research and development spending, including closing its research facility in Sandwich, UK and letting go almost all of the 2,400 employees there. Pfizer also announced it will cut its R&D expenditure by $1–2 billion for the next fiscal year.

25 See John P. Walsh, Wesley M. Cohen, and Charlene Cho, *Where Excludability Matters: Material Versus Intellectual Property in Academic Biomedical Research*. RESEARCH POLICY, 36(8), 1184–1203 (2007), which cited empirical data that indicates 70% of agreements between academia and industry for academic researchers to gain access to industry proprietary materials for the purposes of R&D included reach-through rights on improvements and some restrictions on publication, which may impede future collaborations.

26 University–industry collaborations can restrict or delay academic publication in favor of preserving a company’s proprietary rights. As stated by Eric Campbell, a sociologist at Harvard Medical School in Boston, ‘You should not in any way accept the notion that these giant institutional agreements are without tremendous danger’, see Heidi Ledford, *Drug Buddies*. NATURE, 474(7352), 433–434 (2011) at 434.
Managers, the tension between conflicting priorities of the parties must be recognized and respected in order for the collaboration to be successful:

The two worlds – university and industry – can be bridged. In fact, their widely divergent missions and institutional obligations (public vs. private interests) can be complementary, synergistic, and beneficial to all.27

Public–private collaboration in product development is not a new idea and appears to be an obvious model to explore in the pharmaceutical sector since none of the individual players in the drug discovery and development process have all the necessary skills and resources to research and develop pharmaceutical products alone. Academia is a rich source of basic research and discovery but lacks the funding and translational expertise of how new therapies reach the market. Industry has core competencies in clinical translational activities and procedures required to convert early-stage research into new therapies, but they generally outsource the discovery of new molecules to external partners.28 There are many different models that attempt to foster the translation of ideas from academia to industry as a means to bridge the translation gap. These range from strategic partnerships to joint institutes between industry and academia. The focus of this book is on one particular model referred to herein as the integrated drug discovery and development model.

The integrated drug discovery and development platform is based on a collaborative model whereby the respective expertise of academia and industry are brought together to establish viability in early stage technologies by way of achieving proof of concept. Establishing indications of feasibility in early stage innovations will enable a more informed determination of the technology’s potential and attract investment partners to take it through to commercialization. Currently, there are several public research organizations that have adopted the integrated drug discovery and development platform (referred to collectively herein as

---

integrated drug discovery organizations, to be discussed in greater detail in Chapter 2). These integrated drug discovery organizations have each created an international network of affiliate and partner institutions to support project development by offering access to state of the art facilities, equipment, and resources, as well as technical expertise and business acumen in order to facilitate the translation of basic research into new medicines. The question is whether the current European legal framework supports a drug discovery and development model based on achieving proof of concept through collaborative partnership between industry and academia, as represented by the integrated drug discovery organization.

C. DO THE EXISTING LEGAL REGIMES SUPPORT THE INTEGRATED DRUG DISCOVERY MODEL OF DEVELOPMENT?

Drug research and development is flanked by three regulatory systems: patent law, competition law, and the drug regulation system (i.e. the European Medicines Agency and United States Food & Drug Administration). Many different factors have an interconnected influence on the social, economic, and legal dynamics that affects the pharmaceutical industry and drug discovery and development process. For example, because the cost of pharmaceutical R&D accounts for an ever greater proportion of public expenditure, governments have had to increasingly scrutinize budgets for funding drug discovery and development. This in turn affects industry practices, such as strategic use of intellectual property rights and pricing policies to ensure profitability.29 And, this in turn affects regulator practices to ensure patients’ right to health by pricing pharmaceutical products lower so that patients can have reasonable access to medicines. In other words, the triangulation of competition policy, patent policy, and drug regulation gives rise to a dynamic whereby government wants to foster innovation by providing incentives to industry through granting intellectual property rights while ensuring there are mechanisms and policy tools in place to help control anticompetitive use of such intellectual property rights.30 Because of this ‘give with one


30 A potential conflict can arise from intervention under competition law to prevent the emergence of monopolies by limiting the exploitation of state granted
hand, take with the other’ dynamic, it is understandable why parties to
the drug development process need to be cautious of the potential legal
consequences and pitfalls that may arise from participating in the
integrated drug discovery model of drug discovery and development.31

The European Union clearly recognizes the importance of funding
proof of concept. With a budget of €20 million for 2015, the European
Research Centre (ERC) has agreed to contribute an additional €150,000
per grant to existing ERC grant holders for the purpose of establishing
proof of concept for research arising from ERC-funded projects.32 The
stated objective of the additional grant is to support the development of
a commercialization strategy of ERC-funded research to attract investors
by preparing a ‘package’ that demonstrates, among other things, viability
of the technology and the intellectual property protection strategy. In
2011, a £180 million catalyst fund was made available for the purpose of
establishing proof of concept so that early stage research can proceed to
clinical development.33 Soon thereafter, the UK Medical Research Coun-
cil (MRC) and the University of Dundee announced new funding of

exclusive rights provided under patent law. However, the underlying objective of
both patent and competition law is to ensure ‘dynamic competition’ or innovation
efficiency achieved through encouraging invention, development, and
commercialization of new products for the benefit of the public. See for example
Joseph F. Brodley, The Economic Goals of Antitrust: Efficiency, Consumer
Welfare, Technological Progress. NEW YORK UNIVERSITY LAW REVIEW,

31 The misconceived view of equating patent rights to economic monopolies
give rise to an oversimplified analysis of license agreements under competition
law by neglecting the beneficial effects of patents in terms of dynamic com-
petition. Consequently, inventors can potentially be ‘punished’ under competition
law, which would have the effect of discouraging innovation because the
incentives guaranteed under patent law can be undermined by competition law.
See for example Michael A. Carrier, Unraveling the Patent-Antitrust Paradox.
UNIVERSITY OF PENNSYLVANIA LAW REVIEW, 761–854 (2002) at 763–
764 and Steven D. Anderman and John Kallaugher, Technology Transfer and the
OXFORD UNIVERSITY PRESS ON DEMAND (2006).

32 See ERC Proof of Concept Grant (accessible at https://erc.europa.eu-proof-
concept). Launched in 2011, the ERC ‘Proof of Concept’ funding initiative is
intended to fund high risk/high gain research to ensure full exploitation of the
ideas it funds and is intended to bridge the gap between research and the earliest
stage of marketable innovation.

33 At the 2011 FT Global Pharmaceutical and Biotechnology Conference,
Prime Minister David Cameron specifically recognized the backlog of commer-
cializable projects stuck in the ‘valley of death’. See the transcript of the speech
£14.4 million over a four-year period from July 2012 to July 2016 from a consortium of six pharmaceutical companies for early stage research and proof of concept of new drug treatments.\textsuperscript{34} Similarly in the United States, in response to a growing concern regarding the lack of drug development by the pharmaceutical industry, the government invested US$1 billion to create the National Center for Advancing Translational Sciences in 2012 to reduce the costly and time-consuming bottlenecks in the translational research.\textsuperscript{35}

Although government funding is essential to scientific R&D, collaboration and team science is required to perform the actual R&D, so the collaborative process is not one that can be driven by government alone. The overall evolution of the economy towards a knowledge economy creates an important incentive for constant innovation and application of state-of-the-art scientific information. This very naturally brings together universities and research organizations on the one hand and industry on the other hand. There is literature to suggest that collaboration with private partners secures additional immediate funds for R&D of multiple projects and speeds up the process to commercialization.\textsuperscript{36} Technology transfer drives economic growth and social welfare, especially in health-related technologies.\textsuperscript{37} It is a shortcut to gaining access to promising new

---

\textsuperscript{34} The companies include AstraZeneca, Boehringer Ingelheim, GlaxoSmithKline, Janssen Pharmaceutica NV, Merck-Serono, and Pfizer. See Medical Research Council press release dated May 16, 2012 entitled 'Academia-Pharma Collaboration Attracts £14.4 million Funding in the UK to Accelerate Drug Discovery' (accessible at http://www.mrc.ac.uk/news/browse/academia-pharma-collaboration-attracts-144-million-funding-in-the-uk-to-accelerate-drug-discovery/).

\textsuperscript{35} See www.ncats.nih.gov


\textsuperscript{37} See Rai et al., \textit{supra note 8}. In the drug discovery and development context, any technology transfer platform between university and industry must simultaneously provide financial benefit to the industry partner and promote the interests of public sector researchers. Intellectual property may need to be ‘used creatively to secure efficient pathways across the gap that separates upstream research from downstream products – a gap so economically perilous that it has
discoveries, and that is why governments encourage and promote international collaborations for the development of innovations. To ensure and promote international collaborations, many of the developed countries have focused on providing recommendations and guidelines to universities and public research organizations to develop intellectual property policies to manage intellectual property rights arising from collaborative efforts. For example, in a 2008 Commission Recommendation on the Management of Intellectual Property in Knowledge Transfer Activities and Code of Practice for Universities and Other Public Research Organizations (the ‘Recommendation’), the European Commission specifically recognized the need to develop policies and guidelines for public research organizations to “effectively exploit publicly-funded research results with a view to translating them into new products and services” through public/private collaborations. The purpose of the Recommendation was to set out ‘clear and uniform recommendations and practices that ensure equitable and fair access to intellectual property generated through international research collaborations’.

An unintended consequence of such international collaborations is the potential for competitive conflict which may arise with respect to the intellectual property rights associated with a project that the industry partner may subsequently acquire rights to. Specifically, the collaboration relationship may inadvertently give rise to a violation of competition law due to anticompetitive or exclusionary conduct, such as but not limited to exclusivity agreements with industry partners, grant back restrictions, and refusal to license to third parties. Furthermore, although the bringing together of complementary skills and assets in a collaboration between industry and integrated drug discovery organizations may facilitate innovation by enhancing efficiency and reducing expenditure, the number and ability of potential market actors to enter the market may be limited by such collaboration. Intellectual property law and competition law are intended to be complementary and share the same objective – that is to

earned the “valley of death” moniker’. If the collaboration generates a large number of efficacious drugs, the public becomes the ultimate beneficiary.


Ibid.
promote innovation, competition, and economic efficiency to the benefit of consumer welfare. However, the exercise of intellectual property rights may be considered anticompetitive under certain circumstances.

The tension between intellectual property law and competition law is especially great in the pharmaceutical context where companies often push the use of intellectual property rights to their limits in an attempt to maximize profits. Patents essentially confer monopoly power in the pharmaceutical industry as they are used to gain and maintain an exclusive market share. This in turn attracts criticism from the public of drug companies abusing their monopoly power afforded by patents at the expense of consumer welfare and fair competition. Competition law should rightfully be used to curtail abuses of intellectual property rights when they have clearly been exercised beyond their scope. The question is when does legitimate assertion of intellectual property rights become an abuse in the eyes of competition law? When does competition law cross the invisible line and impinge on the right of exclusive use granted by patent law, thereby eliminating or substantially decreasing the incentives for innovation? The pharmaceutical industry has long maintained that patents are crucial to the financial viability of continued R&D. For instance, four months after Lipitor came off patent in November 2011, generic drug maker Ranbaxy Laboratories became the leading seller of the medication and Lipitor’s worldwide sales dropped by 59% in 2012.

---


43 For example, see Glasgow, supra note 41, who states: ‘Perhaps nowhere is this tension more obvious than in the pharmaceutical industry where intellectual property rights are pushed to their limits in an attempt to maximize profits on popular brand name drugs’. See also Cristian Timmermann and Hank van den Belt, *Intellectual Property and Global Health: From Corporate Social Responsibility to the Access to Knowledge Movement*. LIVERPOOL LAW REVIEW, 34(1), 47–73 (2013) who argued that the realities of the intellectual property system may mean that urgently needed medicines will not be developed at all because they are not profitable, that the existing medicines will not be suitable for countries with a precarious health infrastructure, or treatment of diseases that are prevalent in poorer regions may be ignored.

Without patents, industry could not survive in the costly and risky business of drug development. Similarly, many universities and public research organizations support patents because they need patents to protect the technology they license to industry in exchange for royalties to support continued R&D.\textsuperscript{45} Given the nature of drug discovery and development, it is understandable that industry wants strong intellectual property protection as an incentive for taking the risk to develop early stage discoveries and be rewarded for their innovation should development lead to commercialization. However, improvement innovators need access to the intellectual property of the original innovator to develop improvements for follow-on innovation. The nature of technology-driven industries is such that an innovator will likely be both a licensor (of improved intellectual property) and a licensee (of an earlier innovation which improved intellectual property is based on). Without a balance of intellectual property law and competition policy, a potential hold-up may be created because complex technologies depend on technological inputs from prior innovators. To what extent should competition authorities limit lawfully obtained intellectual property rights in order to encourage innovations based on improvements of protected technologies?

\textsuperscript{45} Johan Bruneel, Pablo d’Este, and Ammon Salter, \textit{Investigating the Factors that Diminish the Barriers to University-industry Collaboration}. RESEARCH POLICY, 39(7), 858–868 (2010). Universities are increasingly proactive in seeking IP protection to manage their collaborations with industry. Over the past thirty years, universities have grown to become economic actors through the rise of university technology transfer offices and their licensing activities. Such efforts have contributed to the commercial focus of universities to create and protect valuable IP for exploitation and financial gain. For example, according to WIPO’s records on international patent filings in 2011, US universities are the most prolific international patent filers among higher education institutions worldwide, accounting for 30 of the top 50 institutions. However, from the university researcher’s perspective, there is conflicting evidence for and against university patenting, exacerbating the difference across universities in terms of financial resources and research freedom. For example, see Lee Davis, Maria T. Larsen, and Peter Lotz, \textit{Scientists’ perspectives concerning the effects of university patenting on the conduct of academic research in the life sciences}. THE JOURNAL OF TECHNOLOGY TRANSFER, 36(1), 14–37 (2011); Valentina Tartari and Stefano Breschi, \textit{Set Them Free: Scientists’ Evaluations of the Benefits and Costs of University-Industry Research Collaboration}, INDUSTRIAL AND CORPORATE CHANGE, 21(5), 1117–1147 (2012); Ani Gerbin and Mateja Drnovsek, \textit{Determinants and Public Policy Implications of Academic-Industry Knowledge Transfer in Life Sciences: A Review and a Conceptual Framework}. THE JOURNAL OF TECHNOLOGY TRANSFER, 1-98 (2015).
After being urged to compete, innovate, and become a solution to the drug discovery and development problem, should participants to collaborative R&D be penalized if they gain market power through legitimate competition? There is literature that supports the position that a company should not be punished for simply being innovative and more efficient than their competitors since this would be detrimental to competition and consumer welfare in the long run. Furthermore, given that competition policy is meant to protect competition as opposed to competitors, it is generally accepted that ‘competition on the merits’ allows a company to force a rival company out of the market or discourage their entry or expansion so long as its conduct is lawful. One way to reduce the conflict between competition policy and intellectual property law in the drug discovery and development context is to define a clear boundary ex-ante that specifically acknowledges and considers the particular dynamics of the pharmaceutical industry and the nature of drug discovery and development so that participants in the collaborative R&D process know in advance what is permissible. Given that competition policy is largely case law driven, whereas intellectual property law has historically been set in legislation and regulatory rule making, any adaptation of the legal system to proactively address the unique and changing circumstances of the pharmaceutical industry should be done at the competition law level, which enjoys greater flexibility.

D. THE INTERSECTION OF COMPETITION LAW AND INTELLECTUAL PROPERTY LAW

One of the first obstacles is how the law will regard and interpret the relationship between public research organizations and industry for the

---


purposes of conducting drug discovery and development. Is the collaboration a research agreement or a transfer of technology for further development? From a competition law perspective, how will the relationship be characterized and which regulation and/or block exemption applies? The overarching question is to what extent does the application of competition law to the integrated drug discovery and development model consider or promote innovation. In other words, do the intellectual property and competition law frameworks support the integrated drug discovery and development model by satisfying the respective objectives of academia (i.e. maintaining traditional university integrity to make publically funded research available to the benefit of society) and industry (i.e. incentivizing and ensuring economic feasibility to justify investment and participation in the collaboration).

The literature indicates that the EU and a number of universities have come to realize that technology transfer can be an attractive source of income to fund the ever-increasing costs of basic research.48 Contrary to

48 See for example Goldie Blumenstyk, *Universities Report $1.8 Billion in Earnings on Inventions in 2011*. THE CHRONICLE OF HIGHER EDUCATION (2012) (accessible at http://chronicle.com/article/University-Inventions-Earned/133972/). In the EU context, Katholieke Universiteit Leuven reported €63.2 million in annual licensing income, generated from around 600 active patent families with close to 90% of those patent families being commercially exploited from contracts with over 2,000 companies. KU Leuven has a proven track record in transferring and translating research into valuable economic activity. See article entitled *KU Leuven – Prestigious University Fosters Innovation-Driven Economy*. THE EUROPEAN TIMES (2014) (accessible at http://www.european-times.com/countries/ku-leuven/). Max Planck Innovation reported €22.5 million in revenue from licensing income and 92 license agreements in 2013 (see http://www.max-planck-innovation.de/en/technology_transfer/successful_track_record/licensing/). The European Commission has argued that while European research institutions are good at producing academic research outputs, they are not as successful as universities in the United States in translating and commercializing the research – the so-called ‘European Paradox’ – which is largely due to a less systematic and professional management of knowledge and intellectual property by European universities. See European Commission, *Improving Knowledge Transfer between Research Institutions and Industry across Europe – Embracing Open Innovation – Implementing the Lisbon Agenda* (2007). The literature generally acknowledges that a ‘European Paradox’ indeed does exist but questions the extent of and the reason for the European underperformance in commercializing publically funded research. See for example Annamaria Conti and Patrick Gaulle, *Is the US Outperforming Europe in University Technology Licensing: A New Perspective on the European Paradox*. RESEARCH POLICY, 40, 123–135 (2011); Neus Herranz and Javier Ruiz-Castillo, *The End of the ‘European Paradox’*. SCIENTOMETRICS, 95(1) 453–464 (2013). One of the
years past, some universities today seem to play an increasing role in and operate on the market in several ways: firstly, they deliver research services to industry via collaboration arrangements; secondly, they operate on the technology market by licensing and assigning their inventions and associated intellectual property rights to third parties; and thirdly, they establish new companies, typically referred to as spin-off companies, which are usually research-intensive small and medium-sized enterprises active in high-tech markets. The commercial nature of these activities carried out by universities gives rise to some interesting and challenging legal questions. One of the issues thus far not widely examined is the impact of competition law on universities and public research organizations, such as integrated drug discovery organizations, operating on the marketplace. At first blush, collaboration agreements between industry and public research organizations do not appear to fall within the scope of Article 101 Treaty of the Functioning of the European Union (TFEU) because there is unlikely to be a limitation on competition. Firstly, public research organizations and industry are most probably not competitors on any market, given the difference in the nature of their respective activities. Secondly, industry is likely the only party to commercialize the results of any successful collaboration, given that industry is the only player in the innovation process that makes products derived from basic research available to and for the benefit of the public. Public research organizations typically have as their mission the carrying out of research ‘for the sake of knowledge’ and disseminating the results of that research via publications and education. Conversely, a company wishes to use the knowledge it creates or otherwise obtains rights to, in an exclusive manner, to obtain a competitive advantage over other companies in the relevant market. How could an agreement between two entities with such different aims ever be restrictive of competition?

Upon closer inspection of the activities of some universities, such public research organizations actually participate in several markets: the market for research services and the market for the licensing of intellectual property rights, known as the ‘innovation market’ and the ‘technology market’, respectively. In a typical university–industry research collaboration, the industry partner will likely require assignment of the top objectives for TTOs is to generate revenue for the university to fund research collaborations, and one of the most common incentives for researchers to engage in knowledge transfer is receiving additional funding for further research. See for example European Commission, DG Research and Innovation, Report of the Knowledge Transfer Study 2010–2012 (RTD/Dir C/C2/2010/SI2.569045 2013).
full ownership of all results arising from the sponsored research project or some form of exclusivity to prevent competitors from benefiting from the knowledge created. From a competition law perspective, this assignment or exclusivity may not necessarily be neutral since the university concerned will likely not be able to exploit its research results by licensing them to third parties, even if the industry partner fails to commercialize the results to its fullest potential. To a certain extent, aggressive and strategic use of intellectual property rights may be compatible with the concept of ‘competition on the merits’, but when commercial practice by intellectual property owners consists of conduct that is prohibited by competition policy as either an exclusionary or exploitative abuse or restriction on competition, competition rules can operate as a limit to the exercise of intellectual property rights.

This book examines the application of Article 101(1) to collaboration agreements between industry and integrated drug discovery organizations and how it impacts innovation in the field of drug discovery and development. The research presents a new perspective on the patent–antitrust intersection, by exploring the competition law assessment of licensing agreements in the light of the economic concept of innovation, licensing efficiency and transactional hazards.

E. OBJECTIVES

The questions and issues this book will attempt to address are as follows:

(a) How do the existing applicable legal frameworks (intellectual property law and competition policy) impact collaboration between

49 OECD Policy Brief, supra note 47 states: ‘Generally, the expression “competition on the merits” implies that a dominant enterprise can lawfully engage in conduct that falls within the area circumscribed by that phrase, even if the consequence of that conduct is that rivals are forced to exit the market or their entry or expansion is discouraged’.

50 Ibid. If the concept of competition on the merits is to be helpful, it must facilitate the task of separating out harmful, exclusionary conduct from healthy competition. Competition is on the merits when it reflects rational commercial conduct based on superior efficiency. See Renato Nazzini, The Foundations of European Union Competition Law: The Objective and Principles of Article 102 (Oxford University Press 2012). The CJEU has established the general principle that conduct is abusive when it restricts competition by means that are inconsistent with the normal profit maximizing strategy of a non-dominant undertaking. See Case C-85/76 Hoffmann-La Roche v Commission [1979] ECR 461 para. 172.
integrated drug discovery organizations and private pharmaceutical companies in the context of the integrated drug discovery and development platform? In other words, can the collaboration between industry and integrated drug discovery organizations be structured in a way that is compliant with existing legal regimes?

(b) To what extent do the existing legal frameworks consider or provide incentives to facilitate innovation in the context of collaborative drug discovery and development?

(c) Given the policy reasons underlying intellectual property law and competition law and the nature of the pharmaceutical sector, will exclusionary conduct found in collaboration agreements between industry and integrated drug discovery organizations, such as but not limited to exclusivity agreements, refusal to license, and exclusive dealings, collectively be necessarily de jure anti-competitive?

This book has two objectives. Firstly, it will analyze how European competition rules apply to the collaboration agreements between industry and integrated drug discovery organizations with respect to the collaborative R&D component and the subsequent technology transfer component, should the collaborative R&D generate positive results. The analysis will form the foundation to assess whether such collaboration agreements give rise to anticompetitive concerns. Based on the assumption that different industries have certain inherent features that give rise to unique issues that affect the industry in question, the purpose of the analysis is to: (i) identify competition law issues that arise from collaborations between industry and public research organizations engaging in collaborative drug discovery and development; and (ii) determine how the interaction between such competition issues and inherent features of the pharmaceutical industry impact the drug discovery and development process.

51 As stated in the OECD Policy Roundtable, *Competition and Regulation Issues in the Pharmaceutical Industry* (DAFFE/CLP(2000)29) 2001: ‘Very few industries are as profoundly influenced by regulation as the pharmaceutical industry. The nature of demand for drugs, the identity of drugs brought to market, and the nature of competition in the drug market over time are all shaped by regulation. There are three main objectives to this regulation: securing a reward to R&D to assure a continuous flow of innovative new medications; ensuring the safety of drugs; and controlling the quantity and enhancing the quality of drug expenditures. The combined effect of this regulation is that competition takes a different form than in other industries … However, the appropriate role for competition is not always plain. Competition advocacy in this industry requires taking a holistic view’.
Secondly, this book aims to draw implications on how the integrated drug discovery model may operate in light of the current trends on the application of competition rules. By analyzing competition issues that are typically addressed ex-post in legal cases and administrative proceedings, which are decided on a case-by-case basis and with perfect hindsight, anticompetitive concerns that arise in the pharmaceutical sector can be identified and used proactively to navigate around potential pitfalls ex-ante. Arguably, legal uncertainty is one of the greatest concerns when parties enter into any legal agreement. The ability to manage potential anticompetitive concerns ex-ante would help de-risk the already precarious process of drug discovery and development. The intention is to identify a possible framework that is compatible with the existing laws and policy to promote efficient drug development and innovation without discouraging international collaboration through the intervention of competition law.52

The hypothesis is that the existing competition law framework fails to consider the specific nature of the pharmaceutical sector by mandating a blanket application of general competition policy without regard to the inherent features of the industry and the risks associated with drug discovery and development.53 If the perspective of competition law is

52 Steven Anderman, EC Competition Law and Intellectual Property Rights in the New Economy. ANTITRUST BULLETIN, 47, 285 (2002), where it is implied that regulation of IPRs by competition policy may not be appropriate in high-technology sectors. According to Anderman, high technology markets are characterized by competition for the market (instead of in the market), and market leadership may be dependent on the exercise of IPRs, meaning dominance may be inevitable but also temporary because of self-regulation when new innovations enter the market. Following such argument, competition law may be over-reactive to the dynamics of the pharmaceutical industry if consideration is not given to the nature of the industry.

53 Some scholars have argued that recent reviews of some regulatory frameworks have seen sector-specific measures being scaled back and general competition law measures gaining a more prominent role. See for example Natascha Freund and Ernst-Olav Ruhle, The Evolution from Sector-specific Regulation towards Competition Law in EU Telecom Markets from 1997 to 2011: Different Effects in Practical Implementation. In 22nd European Regional Conference of the International Telecommunications Society (IT2011), Budapest, 18–21 September 2011. However, proponents of sector-specific rules have argued that general competition law enjoys a hierarchical priority over sector-specific rules but lacks the breadth of objectives expressed by sector regulation. In the context of the Internal Energy Market, it has been suggested that sector rules should have a functional priority regarding their implementation as lex specialis and constitute the context for any potential application of competition law … The
limited to viewing the collaboration agreements with a market-centric focus, then competition law fails to consider how such agreements help overcome problems associated with the innovation process, such as de-risking transactional hazards to facilitate the commercialization of new products. Protecting healthy competition must also include protecting agreements that incentivize collaboration and commercialization which form an essential part of the innovation process. As stated in the final report by the European Commission on the financing of biopharmaceutical product development in Europe:

[The European Commission should recognize the unique structural characteristics of the biopharmaceutical sector (capital-intensive, long time to market, high risk of failure) by considering sector-specific policy measures targeting the special needs of the biopharmaceutical sector. Such sector-specific measures would constitute a new approach in European industrial policy (compared to the current horizontal approach) that could successfully support the future development, innovative capacity and competitiveness of the European biopharmaceutical sector.]

The model proposed by the research emphasizes prioritization of sector-specific rules, use of competition rules as an interpretative tool, limitation of their independent application to cases where sector regulation fails and even then after taking into consideration sector specific context and acceptance of dynamic competition as an orientating framework*, Michael D. Diathesopoulos, *Competition Law and Sector Regulation in European Energy Market after the Third Energy Package: Hierarchy and Efficiency* (University of Cambridge Faculty of Law Research Paper 2012), at 1 and 101. As indicated in the Pharma Sector Report, *supra* note 1, there are unique competition law issues that arise in the pharmaceutical context that require attention, which may provide the basis for supporting the need for sector-specific competition rules.

F. METHODOLOGY

If one accepts the premise that legal research involves the finding, interpretation, application, and/or critique of law and legal rules ‘in context’ (i.e. the law is not and cannot be applied with perfect neutrality), then legal dogmatics alone as a methodology cannot answer questions of what law and policy should be. It needs to be supported by, for example, the social sciences, to provide a more holistic perspective on the way the law operates in a defined context. Legal studies are increasingly becoming less doctrinal and more interdisciplinary. Whether the incorporation of insights from various disciplines in the study of law is considered part of the ‘normal science’ in doctrinal law or whether it constitutes a ‘new’ interdisciplinary or multidisciplinary approach to legal research is debatable. As a result, the methodological approach will not be limited to the traditional analysis of legal issues alone.

---


56 See for example, Jan M. Smits, Law and Interdisciplinarity: On the Inevitable Normativity of Legal Studies. CRITICAL ANALYSIS OF LAW, 1, 1 (2014); Richard A. Posner, The Decline of Law as an Autonomous Discipline: 1962–1987. HARVARD LAW REVIEW, 100, 761 (1987); Brian Z. Tamanaha, Law as a Means to an End: Threat to the Rule of Law (Cambridge University Press 2006) at 151; Jack M. Balkin, Interdisciplinarity as Colonization. WASHINGTON & LEE LAW REVIEW, 53, 949–970 (1996), which stated: ‘interdisciplinary scholarship is now an expected part of a serious scholar’s work at most of the elite law schools. … Because these schools generally are looked up as leaders of academic fashion and because they produce most of the new law professors, one would think that the future of interdisciplinary scholarship looks exceedingly bright’. However, the interdisciplinary approach to the study of law has also been widely criticized. See for example Jan A. Smits, The Mind and Method of the Legal Academic (Edward Elgar Publishing 2012); and Irma J. Kroeze, Legal Research Methodology and the Dream of Interdisciplinarity. POTCHEFSTROOM ELEKTRONIESE LAW JOURNAL, 16(3), 35–65 (2013); Shai Lavi, Turning the Tables on ‘Law and …’: A Jurisprudential Inquiry into Contemporary Legal Theory. CORNELL LAW REVIEW, 96, 811 (2010).

57 As stated by Smits, supra note 56, traditional jurisprudence takes the investigation of the normative meaning as its main focus. It achieves its goal through the interpretation of legal texts. Because the law is increasingly being studied by economists, philosophers, psychologists, and representatives from...
i. Socio-legal Approach

The overall analysis of this book will be carried out through a socio-legal perspective to study how the law interfaces with society within a defined context in which the law operates. In the context of drug discovery and development, the socio-legal approach helps assess and understand the relationship and dynamic interaction between public interests of society (driven by health and welfare), private interests of industry (driven by commercial interests), and the resulting impact law has on society as well as the influence society has on shaping the law. Legitimacy of the law depends both on the consistency and coherence of legal concepts and on its responsiveness to the social context in which the law operates. There is an opportunity in this book to look at the issues from the perspective of a legal practitioner as well as a researcher and combine both empirical and theoretical viewpoints that reflect the way the law interacts with the social environment. This allows the legal system to be understood from the perspective of wider political, economic, and social structures within which the law forms and operates so the system itself and its purpose may be challenged from an exogenous standpoint. Compared to employing mainstream traditional doctrinal methods to the study of law, a socio-legal perspective allows research in law to be conducted other disciplines, the social sciences emphasize positive or empirical characteristics of legal phenomena. What it focuses on is not the normative meaning of legal texts but the reality of law to help clarify different positions on what the law ought to be.

58 See for example Sally Wheeler and Phil A. Thomas, ‘Socio-Legal Studies’ in David J. Hayton (ed.), Law’s Future(s) (Hart Publishing 2002) at 271. See also Philip A. Thomas, ‘Socio-Legal Studies: The Case of Disappearing Fleas and Bustards’ in Philip A. Thomas (ed.), Socio-Legal Studies (Dartmouth Publishing Company 1997). Because drug discovery and development has social welfare, economic, and political implications for society as a whole, all of which have the potential to shape the development of law and legal process, the subject matter lends itself to such an approach. See for example Alain Pottage, The Socio-legal Implications of the New Biotechnologies. ANNUAL REVIEW OF LAW AND SOCIAL SCIENCE, 3, 321–344 (2007).


61 Terry Hutchison and Nigel Duncan, Defining and Describing What We Do: Doctrinal Legal Research. DEAKEN LAW REVIEW, 17(1), 83–119 (2012) at 102.
from a humanistic and social scientific standpoint as a means to understand the law as a reflexive social institution as opposed to merely being a system of inflexible rules and doctrines. Such a perspective supplements conventional legal doctrines and sources such as case law and legal rules and regulations with an anthropological element, which helps situate and frame the law for a more nuanced analysis that reflects changing societal needs and norms.

ii. Proactive Law

Rather than conducting a legal analysis of competition issues alone, this book will proactively explore how the legal environment that impacts the pharmaceutical sector relates to the integrated drug discovery and development model in a broader socio-economic framework. Instead of perceiving law as being a constraint that needs to be reactively complied with, a proactive approach to considering and anticipating what legal issues may arise ex-ante will have a greater likelihood of facilitating a more efficient and effective drug discovery and development model. As an analogy, the law as we currently know it is reactive, like taking insulin therapy for diabetes. Preventive law is like taking prophylactics to delay the progression of diabetes, and proactive law is like adopting lifestyle changes to reduce the chances of the onset of diabetes. The proactive approach can be applied to drug discovery and development as a way to align and articulate various stakeholders’ interests with legal policy objectives as a way to de-risk the process. Competition law analysis needs to be transparent and predictable so that market participants can organize their business efficiently and have the confidence to cooperate and invest, especially when the burden is on the market actors to assess the legality of their practices.

iii. Legal Dogmatics

Legal dogmatics has been defined as ‘the science of investigating the objective meaning on positive legal order’ and ‘a system of statements

---

62 Banakar and Travers, supra, note 60.
about the valid law'. It is typically used to interpret, clarify and evaluate, reformulate, or predict the development of valid legal norms. Legal interpretation requires rationality and acceptability, which can be achieved by analyzing and interpreting statutes, rulings of courts and authorities, policy statements and relevant sector inquiries and reports. In the area of intellectual property right related competition law, anti-competitive conduct is usually analyzed on a case-by-case basis in judgments and decisions of the court and competition authorities. However, decisions relating to the pharmaceutical industry relevant to this particular inquiry are few and far between. The application of competition law to collaboration agreements and associated licensing arrangements is an area of law that has only been addressed for a relatively short period of time by secondary legislation through Commission Regulations. Consequently, case law is practically non-existent and older cases apply an out-of-date style of economic analysis, especially in light of the recent reforms to competition law that adopt a more economic style of analysis. Turning to decisions, guidelines, and

---


67 What was considered a restriction of competition thirty years ago may not be regarded as restriction of competition today. For example, Case 320/87, *Kai Ottung v Klee & Weibach A/S and Thomas Schmidt A/S* [1989] ECR 1177 and Case 65/86 *Bayer AG and Maschinenfabrik Hennecke GmbH v Heinz Sülthöfer* [1988] ECR 5249, which found that royalty payments put licensees at a competitive disadvantage and thus may restrict competition.

68 Commission Regulation No 316/2014 on the application of Article 101(3) of the Treaty on the Functioning of the European Union to categories of...
statements made by the Commission, the authoritative value and the legal effects of such soft law instruments may be questioned as they by nature cannot be legally binding. Commission decisions essentially restate interpretations from case law but also include the Commission’s own interpretation of the law as well as the facts in particular sectors and/or under certain circumstances. As such, their validity and binding effect on the courts is questionable. Although soft law does not have the character of a binding rule of law, it nevertheless creates a legitimate expectation of a rule of conduct or practice that should be followed unless justifiable reasons are given since otherwise the principles of equality of treatment would be infringed.69

iv. Law and Economics

Because competition law and intellectual property law regulate economic activities and incentives to innovate, the integrated drug discovery model clearly lends itself to economic analysis.70 With economic efficiency as one of its core objectives, competition law clearly recognizes the values underlying economic concepts and can benefit from the reasoning and insights of economic theory.71 An economic perspective will give insight into market-based issues to explain the intersection between competition law, intellectual property law, and commercialization in the context of the technology transfer agreements, OJ 2014 L93/17 (‘TTBER’) came into force on March 21, 2014 and Commission Regulation No 1217/2010 on the application of Article 101(3) of the Treaty on the Functioning of the European Union to categories of research and development agreements, OJ 2010 L335/36 (the ‘R&D Regulation’) came into force December 14, 2010.

70 Competition law deals with markets, implying a natural link to economic theory. See Giorgio Monti, EC Competition Policy (Cambridge University Press 2007); Alina Kaczorowska, European Union Law (Routledge 2011).
71 Courts and the Commission decisions frequently use reasoning based on economic theory in conjunction with legal doctrine when applying and interpreting competition law. See for example Case 27/76 United Brands Company and United Brands Continental BV v Commission of the European Communities [1978] ECR 207, para 122, where the Court used economic theories to make a connection between entry barriers and sunk costs. See also joined Cases C-89/85, C-104/85, C-116/85, C-117/85 and C-125/85 to C-129/85, A. Ahlström Osakeyhtiö and others v Commission of the European Communities (Woodpulp), ECR [1993] I-1307, where the ECJ relied on economic analysis of the market to evaluate the Commission’s assessment of an alleged concerted practice.
pharmaceutical industry. Law and economics identifies economic efficiency as its policy goal and may be seen as an expression of legal pragmatism because it challenges the claim that the law is closed to social and economic pressures.\textsuperscript{72} Normative law and economics suggest that legal rules that generate the most social welfare are the only types of rules that should be accepted because they represent the collective interests of society as a whole.\textsuperscript{73} However, not everyone accepts the premise that the main objective of society is to achieve more social welfare by satisfying the aggregate of individual preferences.\textsuperscript{74} In the present context, understanding the economic rationale and effects of different licensing practices is crucial to understanding their effect on both innovation and competition. As such, economic analysis can complement traditional legal analysis of competition law.\textsuperscript{75}

\textbf{v. Empirical Research}

Empirical research enables knowledge to be gained by direct interaction through systematic collection and analysis of information. Semi-structured interviews of four integrated drug discovery organizations were conducted, and collaboration agreements entered between each of the integrated drug discovery organizations and an industry partner were collected. Among other things, the agreements illustrate how collaboration with industry is structured, how intellectual property rights that arise from the collaboration are managed and commercialized, and what factors affect the selection of projects. The contractual terms of the collaboration agreements were analyzed with respect to the competition law framework. These results will be reviewed and analyzed in Chapter 6.


\textsuperscript{73} Louis Kaplow and Steven Shavell, \textit{Fairness Versus Welfare} (Harvard University Press 2009).


\textsuperscript{75} Relying on economic theory alone may be problematic as economic considerations fail to consider other values and goals inherent in competition law such as market integration or the protection of SMEs. See Valentine Korah, \textit{An Introductory Guide to EC Competition Law and Practice} (9th edn, Hart Publishing 2007). Economic analysis of the law also has its critics. Law and economics is premised on rationality and pragmatism and should that assumption fail because firms may behave differently than individuals, the predictive value of economic analysis also fails. See Richard A. Posner, \textit{The Economic Approach to Law. TExAS LAW REVIEW}, 53, 757 (1975).
in furtherance of the analysis on the applicability of the Regulation No 1217/2010 on the application of Article 101(3) to research and development agreements (the ‘R&D Regulation’),\textsuperscript{76} and Commission Regulation No 316/2014 on the application of Article 101(3) to technology transfer agreements (the ‘TTBER’),\textsuperscript{77} and Article 101(3) exemptions to the collaboration agreement.

G. THE ROAD MAP

Having introduced the problem with respect to the current drug discovery and development process in this chapter, Chapter 2 will provide some background information on how the pharmaceutical industry functions and explain how and why traditional drug development may no longer be an efficient model. In that context, the integrated drug development model will be introduced as an alternative that fosters university–industry collaboration to de-risk the drug discovery and development process while facilitating innovation through achieving proof of concept. For the sake of comparison, Chapter 2 will briefly consider other approaches to the open innovation model and their possible role in the drug development process. Chapter 2 concludes with a summary analysis of the three drug development models (traditional technology transfer, integrated drug development, and open science) and proposes that the integrated drug development model (as a version of the triple helix model of innovation)\textsuperscript{78} merits further investigation into whether international collaborative R&D between industry and public research organizations is supported by existing legal and regulatory frameworks.

Chapter 3 introduces the intersection between competition policy and intellectual property rights in the context of collaborative research in the pharmaceutical sector and as it relates to the drug discovery and development process. It further explores the applicability of Article 101 to the collaboration agreement that governs the relationship between industry and integrated drug discovery organizations. The main focus of this chapter is to analyze and determine whether the collaboration agreements between industry and integrated drug discovery organizations fall within the purview of Article 101. The chapter concludes with a

\textsuperscript{76} R&D Regulation, \textit{supra} note 68.

\textsuperscript{77} TTBER, \textit{supra} note 68.

Introduction

discussion of the effects of applying Article 101 to collaborative drug discovery and development and argues for sector-specific considerations, given the unique dynamics of the pharmaceutical sector.

Chapter 4 introduces the R&D Regulation and considers whether the R&D component of the collaboration agreement between integrated drug discovery organization and industry falls within the purview of the R&D Regulation. It focuses on the concept of R&D poles and how they may restrict collaborative innovation in the drug discovery and development context. The chapter concludes with an argument for the need to support collaborative R&D in drug discovery and development, despite potential restrictions on the innovation market.

Chapter 5 introduces the TTBER and considers whether the licensing aspects of the collaboration agreement between integrated drug discovery organization and industry falls within the purview of TTBER. The chapter analyzes various contractual restrictions typically found in technology transfer agreements and how such restrictions are viewed from the perspective of competition policy.

Chapter 6 analyzes the contractual terms of the collaboration agreements collected from each of the four integrated drug discovery organizations with reference to the R&D Regulation and TTBER. Analysis of Article 101(3) exemptions will also be discussed with respect to whether they apply to the collaborative agreements should the agreements not qualify for exemption under the block exemptions.

Chapter 7 summarizes the legal implications of the integrated drug discovery model and discusses various concluding remarks, observations, and comments relating to integrated drug discovery in the larger innovation framework.