

Rijksdienst voor Ondernemend Nederland

Bijblad bij De Industriële Eigendom nummer 1 - januari 2019 – jaargang 87

Het Bijblad bij De Industriële Eigendom (BIE) is een digitale kwartaaluitgave van Octrooicentrum Nederland, onderdeel van Rijksdienst voor Ondernemend Nederland.

Inhoud

Officiële mededelingen Nationale Ontwikkelingen (incl. Wetswijzigingen en Kamerstukken) Internationale Ontwikkelingen Jurisprudentie

Officiële mededelingen

De officiële mededelingen bestaan uit vijf categorieën: Sluitingsdata, Octrooigemachtigdenregister, Mededelingen Examencommissie, Mededelingen Octrooiregister en Mededelingen Octrooikennis en -voorlichting Een categorie wordt alleen genoemd als er mededelingen zijn.

- Sluitingsdata [lees meer]
 - Octrooigemachtigdenregister [lees meer]
- Mededelingen Octrooiregister
 - Periodiek Administratief Overleg [lees meer]
 - Benelux Patent Platform Release 1.9 [lees meer]
 - Mededelingen Octrooikennis en -voorlichting
 - Octrooicentrum Nederland sluit aan bij MKB Connect Team [lees meer]
 - Vernieuwde versie Espacenet [lees meer]
 - Wet bescherming bedrijfsgeheimen [lees meer]
 - DesignEuropa Awards [lees meer]
 - Promotie octrooiadviseur Peter van Dongen [lees meer]
 - Octrooi- en evenementenkalender [lees meer]

<u>naar boven</u>

Nationale Ontwikkelingen (incl. Wetswijzigingen en Kamerstukken)

- Cijfermatige informatie Octrooicentrum Nederland [lees meer]
- Beleidsevaluatie Nederlandse Intellectueel Eigendomsbeleid [lees meer]
- Leidraad wettelijk advies [lees meer]
- Apothekersvrijstelling [lees meer]
- Periodiek overleg met de Orde van Octrooigemachtigden [lees meer]
- Rechtbank Den Haag beslist over teff-octrooien [lees meer]

Internationale Ontwikkelingen

Het Bijblad doet in deze rubriek verslag van de belangrijkste internationale ontwikkelingen.

- Mondiaal
 - Standing Committee on the Law of Patents (WIPO) [lees meer]
- Europees
 - Administrative Council [lees meer]
 - Uitspraak Technische Kamer EOB [lees meer]

naar boven

Jurisprudentie

Het Bijblad houdt u op de hoogte van de uitspraken die Octrooicentrum Nederland heeft gedaan in eerste aanleg of in bezwaar. Tevens vindt u hier de uitspraken van de Rechtbank en de Afdeling Bestuursrechtspraak van de Raad van State, voor zover Octrooicentrum Nederland bij die zaken betrokken was. Bovendien zullen uitspraken van gerechtelijke instanties worden opgenomen die van belang zijn voor de praktijk van Octrooicentrum Nederland.

Aanvullende beschermingscertificaten

BIE 2019, nr. 1, Hof van Justitie EU, 25 oktober 2018, Boston Scientific Ltd / Deutsches Patent- und Markenamt [lees meer] BIE 2019, nr. 2, Conclusie van de Advocaat Generaal, Hof van Justitie EU, 13 december 2018, Abraxis / Comptroller General of Patents [lees meer] Overig

BIE 2019, nr. 3, Rechtbank Den Haag, 21 november 2018, Ancientgrain / Bakels [lees meer] BIE 2019, nr. 4, Rechtbank Den Haag, 21 november 2018, CDVI / IMPRO c.s. [lees meer]

naar boven

Colofon

Redactiesecretariaat: mw. L.C.J.P. de Vlieger lydia.devlieger@rvo.nl Hier kunt u zich ook afmelden als u het Bijblad niet meer wenst te ontvangen.

Sluitingsdata 2019

Octrooicentrum Nederland is in 2019 op de volgende dagen gesloten:

dinsdag 1 januari (Nieuwjaarsdag) maandag 22 april (Tweede Paasdag) donderdag 30 mei (Hemelvaartsdag) maandag 10 juni (Tweede Pinksterdag) woensdag 25 december (Eerste Kerstdag) donderdag 26 december (Tweede Kerstdag)

Inschrijvingen en doorhalingen in het Octrooigemachtigdenregister

Op 19 december 2018 zijn ingeschreven en beëdigd:

- Mw. Dr. B. den Adel
- Dhr. J. Paredes Rojas
- Dhr. Dr. ir. L.P.A. Mooij

Op 13 december 2018 is op eigen verzoek de heer ir. A.W.J. Zeestraten uitgeschreven uit het octrooigemachtigdenregister.

Op 1 januari 2019 is op eigen verzoek de heer ir. C.H. Riem uitgeschreven uit het octrooigemachtigdenregister.

Op 29 januari 2019 zijn op eigen verzoek de heer dr. H.J.R. de Boer en de heer drs. L.M.J. Bessems uitgeschreven uit het octrooigemachtigdenregister

Hier kunt u het octrooigemachtigdenregister raadplegen: <u>Octrooigemachtigdenregister</u>.

Periodiek Administratief Overleg

Onder leiding van Octrooicentrum Nederland (OCNL) is er op 20 november 2018 opnieuw een bijeenkomst geweest van het zogeheten Periodiek Administratief Overleg (PAO). Dit PAO is voor OCNL belangrijk als platform om ontwikkelingen en eventuele knelpunten direct met de klant te kunnen bespreken. Tegelijkertijd biedt het PAO voor klanten van OCNL de gelegenheid om feedback te geven en om ook zelf (nieuwe) ontwikkelingen te delen. Met 17 deelnemers aan het PAO die 12 verschillende kantoren vertegenwoordigden werd de bijeenkomst goed bezocht.

Dit keer was er onder meer aandacht voor de externe gebruikersenquête inzake de verdere ontwikkeling van het Benelux Patent Platform (BPP). De onderwerpen in deze gebruikersenquête hadden betrekking op het octrooiregister (eRegister), de indiening van octrooiaanvragen (eFiling), de interface voor MyPage en enkele algemene onderwerpen (zoals de Patent Portal Generic). De uitkomsten hiervan werden tijdens dit overleg gedeeld. Over het algemeen was het beeld over het functioneren van het Octrooiregister, Online filing en MyPage positief.

Daarnaast was er tijdens het overleg aandacht voor de huidige werkvoorraden bij OCNL, de Espacenet-publicaties en de volgende release van BBP in januari 2019.

Voor het volgende PAO (in het voorjaar van 2019) staat onder andere de Algemene Verordening Gegevensbescherming (AVG) centraal. Voor het PAO kan men zich aanmelden bij Lydia de Vlieger (<u>lydia.devlieger@rvo.nl</u>).

Benelux Patent Platform Release 1.9

Op 7 januari 2019 is release 1.9 succesvol geïmplementeerd. De aanpassingen die hiermee zijn doorgevoerd in het Benelux Patent Platform (BPP) zijn het gevolg van de in werking getreden Algemene Verordening Gegevensbescherming (AVG). Het voornaamste uitgangspunt bij deze release is dat via het online dossier enkel die documenten zichtbaar zijn die op basis van de Rijksoctrooiwet 1995 (ROW) gepubliceerd moeten worden: beschrijvingen, conclusies, nieuwheidsrapporten en uittreksels. Dit blijft onveranderd. Alle overige documenten (die voor OCNL overigens wel van belang zijn voor uitvoering van de ROW) kunnen via het online dossier dus niet meer geraadpleegd worden. Daarnaast kan het voorkomen dat in de wel zichtbare documenten bepaalde persoonsgegevens zijn uitgevlakt of geanonimiseerd.

Voor meer informatie kunt u contact opnemen met de Publieksvoorlichting van Octrooicentrum Nederland: 088-0426660 of mailen naar <u>octrooicentrum@rvo.nl</u>.

Octrooicentrum Nederland sluit aan bij MKB Connect Team

Octrooicentrum Nederland (OCNL) is sinds oktober 2018 officieel aangesloten bij het MKB Connect Team van The Hague Security Delta (HSD). HSD is een onafhankelijke netwerkorganisatie waarbinnen bedrijven, overheden en kennisinstellingen samenwerken bij de ontwikkeling van innovaties rondom cybersecurity. De partijen werken aan innovatieve oplossingen die de wereld veiliger maken en economische groei voor Nederland opleveren, door veiligheidsvraagstukken en kennis te delen. Binnen het MKB Connect Team informeert OCNL innoverende (startup-) bedrijven over intellectueel eigendom. Meer informatie op:

https://www.thehaguesecuritydelta.com/about/sme-connect

Vernieuwde versie Espacenet

Espacenet is de octrooidatabank die door het Europees Octrooibureau (EOB) gratis ter beschikking wordt gesteld en toegang biedt tot ruim 100 miljoen octrooipublicaties. De afgelopen twee jaar heeft het EOB gewerkt aan een beta-versie van Espacenet en is een test-versie reeds gelanceerd. De beta-versie is moderner, dynamischer, intuïtiever en is geoptimaliseerd om op verschillende apparaten te werken, waaronder desktop-pc's, tablets en smartphones. Vrijdag 16 november 2018 organiseerde het EOB een workshop voor de nationale octrooibureaus waarin de beta-versie werd gepresenteerd. OCNL was hier ook bij aanwezig. De komst van de vernieuwde versie brengt veranderingen voor OCNL met zich mee: medewerkers krijgen een opleiding, opleidingsproducten worden aangepast en er wordt gewerkt aan vertalingen van de (Engelstalige) Espacenet-schermen en helpteksten voor de Nederlandstalige versie. De definitieve beta-versie wordt in het tweede kwartaal van 2019 beschikbaar; op een later moment dit jaar komen de (vertaalde) nationale versies beschikbaar.

Wet bescherming bedrijfsgeheimen

Op 23 oktober 2018 is de Wet bescherming bedrijfsgeheimen (Wbb) in werking getreden. Deze wet maakt duidelijk wat een bedrijfsgeheim is, aan welke voorwaarden bedrijfsinformatie en knowhow moeten voldoen om een bedrijfsgeheim te kunnen zijn en welke juridische stappen er genomen kunnen worden om tegen inbreuk op te treden. De Wbb komt voort uit een Europese richtlijn. Doordat alle EU-lidstaten deze richtlijn moeten invoeren zijn de spelregels nu in heel Europa gelijk. Hierdoor krijgen ondernemers meer rechtszekerheid bij het optreden tegen inbreuk op een bedrijfsgeheim.

Octrooicentrum Nederland en het Benelux-Bureau voor de Intellectuele Eigendom (BBIE) hebben een voorlichtingscampagne over bedrijfsgeheimen ontwikkeld. Deze campagne is op 3 december 2018 van start gegaan en loopt tot 27 januari 2019. Het doel van de campagne is bekendheid genereren bij ondernemers over de functie en de mogelijkheden van bedrijfsgeheimen bij het beschermen van informatie en kennis. Hierbij ligt de focus op het realiseren van een zo groot mogelijk bereik onder mkb-bedrijven in de zakelijke dienstverlening, (tech)startups, scale-ups en bedrijven die de grens over gaan.

De campagne bevat onder meer:

- een onepager website: <u>www.bedrijfsgeheim.nl</u>. Op deze site wordt uitgelegd wat een bedrijfsgeheim is, welke voorwaarden hiervoor gelden, welke maatregelen je moet nemen en bij welke organisaties je meer informatie kunt vinden.
- Via online advertising, websites en onze eigen social media kanalen zullen we ondernemers met de mogelijkheden van bedrijfsgeheimen kennis laten maken.
- De brochure 'Bedrijfsgeheimen bij technische innovaties' is geüpdatet.
- De verschillende IE-platformpartners (BBIE, Raad voor plantenrassen en de Kamer van Koophandel) ontsluiten actief informatie over de Wbb en ontwikkelen nieuwe content en bestaande voorlichtingsmiddelen worden geüpdatet.
- Intermediaire organisaties die belangen van ondernemers behartigen zijn verzocht om aandacht aan bedrijfsgeheimen en de Wbb te besteden.

DesignEuropa Awards

Op 27 november 2018 vond de bekendmaking plaats van de DesignEuropa Awards. Het was de tweede keer dat het Bureau voor intellectuele eigendom van de Europese Unie (EUIPO) deze prijs op het gebied van vormgeving en ontwerpbeheer uitreikte onder houders van ingeschreven Gemeenschapsmodellen. In de categorie SME (small and medium sized enterprises) ging de prijs naar het Air.Go 2.0, een automatisch bagage-inchecksysteem, eigendom van de Deense firma Marcus Pedersen ApS, en ontworpen door Sara Clement.

De Industry Award werd gewonnen door Siemens Healthcare GmbH voor het patiëntgerichte ARTIS Pheno: een angiografiesysteem met een robotarm die 2D- en 3D weergaven kan maken tijdens bloedvatonderzoeken. De ontwerpers van het systeem zijn Nadja Roth en Tobias Reese. De Lifetime Achievement Award werd uitgereikt aan Hartmut Esslinger, een Duitse ontwerper die samenwerkte met Steve Jobs en Apple, en in de jaren 1980 de ontwerptaal 'Snow White' ontwikkelde. Verder ontwierp hij voor bedrijven als Sony, Microsoft, Lufthansa en Disney. Nederland heeft zich kandidaat gesteld om de uitreiking van de DesignEuropa Awards in 2020 te organiseren.

Promotie octrooiadviseur Peter van Dongen

Octrooiadviseur bij Octrooicentrum Nederland, Peter van Dongen, is op 6 december 2018 gepromoveerd aan de Vrije Universiteit van Amsterdam. Onderwerp van zijn onderzoek was 'Hoe academische octrooien vorm geven aan innovaties'. Met het oog op de discussies over de impact van wetenschappelijk onderzoek in onze samenleving, kan de exploitatie van academische octrooien duidelijk aantonen hoe universiteiten bijdragen aan technologische innovaties. In afgelopen decennia zijn de wettelijke taken van universiteiten om onderwijs te geven, onderzoek uit te voeren en kennis over te dragen naar de maatschappij uitgebreid met de taak om onderzoeksresultaten te valoriseren. Dit proces van kennisvalorisatie kan op verschillende manieren worden ingericht waaronder het gebruik van academische octrooien. Vier factoren, te weten wetgeving, beleid, bestuur en het gedrag van wetenschappers kunnen de maatschappelijke impact van academische octrooien in verschillende mate bepalen. Deze factoren bepalen namelijk hoe academische octrooien kunnen worden omgezet naar technologische innovaties. Met name de rol van ondernemende wetenschappers, die een geoctrooieerde uitvinding in een universitair spin-off bedrijf exploiteren, blijkt hierbij van cruciaal belang. Voor de dissertatie klik hier.

How Academic Patents shape Innovations

A Study into Factors that determine the Use of Patents in pathways of Research Commercialisation

Peter van Dongen | 2018

How Academic Patents shape Innovations

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Peter van Dongen 2018

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VRIJE UNIVERSITEIT

How Academic Patents shape Innovations

A Study into Factors that determine the Use of Patents in pathways of Research Commercialisation

ACADEMISCH PROEFSCHRIFT

ter verkrijging van de graad Doctor of Philosophy aan de Vrije Universiteit Amsterdam, op gezag van de rector magnificus prof.dr. V. Subramaniam, in het openbaar te verdedigen ten overstaan van de promotiecommissie van de Faculteit der Bètawetenschappen op donderdag 6 december 2018 om 9.45 uur in de aula van de universiteit, De Boelelaan 1105

door

Peter Harry van Dongen

geboren te 's-Gravenhage

promotor:

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Account

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- Van Dongen, P., Tak, H. and Claassen, E. (2018). Policies and patenting to stimulate the biotechnology sector: Evidence from the Netherlands. *Science and Public Policy* (in press), <u>https://academic.oup.com/spp/advance-article/doi/10.1093/scipol/scy044</u>

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- Van Dongen, P., El Hejazi, Z. and Claassen, E. (2017). Analysing patent terms and citations to determine the value of gene therapies, *Journal of Commercial Biotechnology*, 23, 2, 61-73
- Sekhon, J. and Van Dongen, P. (2018). Embedding Intellectual Property Law at Dutch and British universities, *Nottingham Law Journal* (in press)

Aan al die wetenschappers, die tijdens hun onderzoek meer inzicht in de materie proberen te verwerven en hun ervaringen gedurende dit onderzoek met mij hebben willen delen, en aan mijn collega's, vrienden en familie die elke dag de moeite waard maken.

Voor Fien, Karel en Lieke, op wie elke vader onvoorstelbaar trots zou zijn, en voor mijn levenskameraad 'Ies' met haar humor, liefde en vreugde.

In liefdevolle herinnering aan mijn ouders E.M.P. van Dongen-van Driem en H.Th. van Dongen, die hun zoon op zo'n jonge leeftijd al veel ruimte konden geven.

Table of contents

Chapter 1

Introduction	

16

12

l.I.	What	is this thesis about?	17
1.2.	Resea	rch issues and objectives	19
1.3.	Conce	ptual framework and research questions	20
1.4.	Litera	ture review supporting the conceptual and	24
	analyt	ical framework	
	1.4.1	Patents and economic growth	24
	1.4.2	Knowledge spillovers and innovations	25
	1.4.3	The effects of innovation policies, IP laws and regulations on academic patenting	26
	1.4.4	Organisation and governance of university technology transfer processes	27
	1.4.5	Scientists' engagement with research commercialisation, motivations and incentives	28
	1.4.6	Identification, exploitation and value of academic patents	30
	1.4.7	The position of patents in the 'Societal Impact Value Cycle'.	32
1.5.	Thesis	s outline	33
	Apper	ndix	

Chapter 2	Academic inventions and patents in the Netherlands: A case study on business sector exploitation	38
2.1.	Introduction	40
2.2.	Background	40
2.3.	Methodology and information sources	41
2.4.	Results	43
	2.4.1. IP-based output: patents and university spin-offs	43
	2.4.2. Survey findings on commercialisation, exploitation and value of academic patents	44
2.5.	Limitations	49
2.6	ConclusionsAppendices	49

Chapter 3	Policies and patenting to stimulate the biotechnology sector: Evidence from the Netherlands	54
3.1.	Introduction	56
	3.1.1. General	56
	3.1.2. The innovation system and biotechnology sector in the Netherlands	57
3.2.	Theory and hypotheses	57
3.3.	Methodology and data resources	60
3.4.	Results	61
	3.4.1 Overall numbers of biotechnology patent applications	61
	3.4.2 BioPartner's effect on the filings of academic biotechnology patent applications	64
	3.4.3 Origin, appropriation and use of academic	65
	biotechnology patent applications	
3.5.	Limitations	70
3.6	Conclusions and discussion	71
Chapter 4	Research commercialisation in Europe: a matter of governance at university Technology Transfer Offices?	76
4.1.	Introduction	78
4.2.	Theory and hypotheses	79
4.3.	Methodology and data resources	81
4.4.	Results	83
4.5.	A case study on the impact of university TTO governance models in the Netherlands	85
4.6	Limitations	91
4.6.	Conclusions and discussion	91
Chapter 5	The relationships between university IP regimes, scientists' motivations and their engagement with research commercialisation in Europe	96
5.1.	Introduction	98
	5.1.1. Background	98
	5.1.2. University IP regimes and patent-based research	98
	5.1.3. Individual motivations of scientists to engage with	99
	with patent-based research commercialisation	

5.2.	Methodology and information sources	100
5.3.	Results	102
5.4.	Limitations	109
5.5.	Conclusions and discussion	110
Chapter 6	The value of academic patents for university spin-offs: A case study of gene therapies	114
6.1.	Introduction	115
6.2.	Patented academic gene therapies in the life sciences sector and their value	116
6.3	Methodology and data resources	117
6.4.	Overall results	120
6.5	A case study about patent citations and market capitalisation for a university spin-off	123
6.6.	Conclusions and discussion	126
Chapter 7	Conclusions and discussion	130
7.1.	Synopsis	131
7.2.	Main findings and conclusion	132
7.3.	The use of academic patents in relationship with	134
7.4.	Scientists' motivations to file patents and their relationship with employment growth	137
7.5.	University IP regimes and the value of academic patents exploited by spin-offs	140
7.6.	Limitations and suggestions for further research	143
References		148
Glossary		162
Summary		166
Dankwoord		170
About the au	ithor	174

List of figures and tables

Figure 1.1.	Factors a, b, c and d contributing to the utilisation of	21
	academic patents and their socio-economic impact	•••
Table 1.1.	The analytical framework with research questions, methodologies and data	23
Figure 1.2.	Key actors in processes of technology transfer and research commercialisation	27
Figure 1.3.	Factors that can influence scientists' engagement with research commercialisation	29
Figure 1.4.	Theoretical framework	31
Figure 1.5. Appendices	Topical relationships in this thesis	35
Table 2.1.	Utilisation of academic patents	45
Table 2.2.	Commercial relevance of academic patents	46
Table 2.3. Appendices	Exploitation and valuation of academic patents	47
Figure 3.1.	Research funding in the Netherlands and transfer of of biotechnology patents	58
Figure 3.2.	Overall numbers of biotechnology patent applications filed by Dutch organisations	62
Table 3.1.	Top 10 Dutch biotechnology patent applicants	62
Figure 3.3.a	Transfer of BioPartner funded patent applications	63
Figure 3.3.b	All Dutch biotechnology patent applications	63
Table 3.2.	Numbers of academic biotechnology patent applications categorised by their applicants and time period	64
Figure 3.4.	Number of annual academic biotechnology patent applications in the Netherlands	66
Figure 3.5.	Numbers of academic biotechnology patent applications categorised by their university of origin, before (1990 -99) and since the start of the BioPartner programme (2000-09)	66
Figure 3.6.a	Most important applicants of academic biotechnology patent applications before the BioPartner programme, 1990 -1999	66
Figure 3.6.b	Most important applicants of academic biotechnology patent applications since the start of the BioPartner programme, 2000 -2009	66
Figure 3.7.	Biotechnology patent applications filed by Dutch universities and Research Foundation STW before (1990 -99) and since the start of the BioPartner programme (2000-09)	67

Table 3.3.	Relative importance of the use of academic biotechnology patents,	69
	categorised per type of organisation (percentage of interviewees with	
	positive responses)	
Figure 3.8	Numbers of annual academic patent applications and academic	70
	biotechnology patent applications in the Netherlands	

Appendix

Table 4.1.	Names and description of university technology transfer governance models and the location of technology transfer offices	79
Table 4.2 .	Summarized statistics	83
Table 4.3.	Relationships between TT governance models and scientists engaged with research commercialisation at universities in Europe	84
Table 4.4.	TT governance models and the location of university TTOs for eight universities in the Netherlands	86
Table 4.5.	Summarised statistics for eight universities in the Netherlands	87
Table 4.6.	Relationships between TT governance models and scientists engaged with research commercialisation in the Netherlands	88
Figure 4.1.	Six categories of academic patents before 2002 and after the implementation of different TT governance models	89
Figure 4.1.a	Classical TT governance model at a centralised TTO	89
Figure 4.1.b	Autonomous TT governance model at a decentralised TTO	89
Figure 4.1.c	A discipline-integrated TT governed model at a regionalised TTO	89
	applicants before (1993 - 2003) and after the implementation of university technology transfer governance models (2004 -2014)	
Table 5.1.	Typology of university intellectual property regimes for research commercialisation in Europe	99
Table 5.2.	Summarised statistics about European scientists' engagement with research commercialisation, patenting and spin-offs (2010-2015)	103
Table 5.3.	Relationships between university IP regimes, scientists' drivers and their engagement with research commercialisation, patenting and spin-off companies	104
Figure 5.1.	Scientists' RC engagement in relationship with 17 variables	105
Figure 5.2.	Scientists' RC engagement vs. scientists' drivers	106
Figure 5.3.	Scientists' RC engagement vs. their university IP regimes	106
Figure 5.4.	Scientists' RC engagement vs. disciplines	106
Figure 5.5.	Scientists' RC engagement vs. university positions	106
Figure 5.6.	Patenting by disciplines	107
Figure 5.7.	Patenting vs. university positions	107
Figure 5.8.	Spin-off creation vs. disciplines	107

Figure 5.9.	Spin-off creation vs. university positions	107
Table 5.4.	Relationships between research commercialisation, studied variables	108
	and other indicators at four European universities and their IP regimes	

Appendices

Figure 6.1.a	Annual number of gene therapy patent applications	119
Figure 6.1.b	Development in numbers of annual life sciences patent applications	119
Table 6.1.	Applicants, inventors and licensees of gene therapy patents filed in 1995	120
Table 6.2.	Patent terms vs. parameters of gene therapy patents filed in 1995	120
Table 6.3.	Comparison of the number of (self-) citations in subsequent	121
	patent applications to patents filed in 1995 with three reference patents	
Figure 6.2.a	Number of citations to the Crucell US6033908 patent in other	122
	patent applications per year	
Figure 6.2.b	Number of citations to Genentech US427224 patent in other patent	122
	applications per year	
Table 6.4.	Number of gene therapy patent applications per company filed	123
	between 1995 and 2005 in three domains	
Figure 6.3.	Comparison of the number of citations to one patent from Crucell	123
	and twelve patents from Chiron- Viagene Inc. between 1995 and	
	2015	
Table 6.5.	Vaccines based upon Crucells' proprietary PER.C6 technology	124
Figure 6.4.	Time lag effect between the number of citations by third parties	125
	to Crucells US6033908 and its market capitalisation between 2000 and 2010	
Appendices		

Table 7.1.	Factors determining the socio-economic impact, use and yield of	133
	academic patents	
Figure 7.1.	Factors determining the commercialisation of academic	134
	patents in the Societal Impact Value Cycle	

Chapter 1

INTRODUCTION¹

¹ This chapter is based on following publication:

Van Dongen, P. (2011). The role of intellectual property rights in the process of knowledge valorisation and regional economic development, in *'Institutions and Regulations for Economic Growth?*', Edward Elgar Publishing ltd. UK, edited by E.F.M. Wubben, <u>https://EconPapers.repec.org/14256.4</u>

Parts of this chapter have been presented at an OECD, EC and EPO conference 'Creating markets for research results' in Munich, June 2013, <u>Creating markets from research results Conference report.pdf</u>

1.1 What is this thesis about?

Technological innovations are the driving force for economies (Baumol, 2004) and as economies become more open and interdependent, these innovations have become of vital importance for well-being in industrialised countries (Gould and Gruben, 1996). Research commercialisation leading to technological innovation has been regarded as one of the important factors contributing to labour productivity growth and the market introduction of new products (Bottazzi and Peri, 1999). For some decades now, the commercialisation of scientific research has contributed to companies' innovations and the flows of university-industry knowledge and technology transfer are significant (Brody, 2016). Some of these technological innovations originating from scientific research have revolutionised our daily lives, e.g. computers, the internet and Google (Isaacson, 2014). Patented academic biotechnology research findings like recombinant DNA, the PCR method and CRISPR-Cas for gene editing have contributed significantly to the production of drugs, vaccines and medical care (Patzelt and Brenner, 2008).

Although the contribution of scientific research to technological innovations is beyond discussion, it is still inherently difficult to quantify the socio-economic impact of scientific research. Given the decreasing budgets for scientific research funding it is important for scientists to be able to produce quantitative, reliable facts and figures about the societal impact of their research. Some economists found that at least 10 % of the innovations would have been delayed in absence of public research (Mansfield, 1991) while others claim that most of the technical innovations of recent date originate from publicly funded scientific research (e.g. Mazzucato and Perez, 2014). In the process of leveraging academic knowledge into the innovation ecosystem (Van den Burgwal et al., 2018) the commercialisation of academic patents can play a significant role and provide relevant insights, since they are an important open source of literature (Tijssen et al., 2000) and contribute to the transfer and use of academic inventions by companies (Siegel et al., 2003). Such academic inventions are often based upon results of years of scientific research at universities (OECD, 2003).

Focussing on the socio-economic impact of academic patents and considering that many governments developed innovation policies in order to boost research commercialisation, it is surprising that neither their impact enabled by these policies, nor their exploitation in the business sector have been studied extensively, longitudinally or empirically (Kaufmann, 2011; Partzelt and Brenner, 2008). To date, despite the important role of universities in the process of academic patenting, evidence-based data showing if, how and why scientists are engaged in this process are limited (Perkmann et al., 2013). Patent awareness, described as being knowledgeable about patent law, use of patent information and functions of patents (Pitkethly, 2012), can be an important factor contributing to research commercialisation, but little is known about the levels of scientists' motivations to file patents have been hard to identify and are either incomplete or valid for a limited number of countries and scientific disciplines (D'Este and Perkmann, 2011). If such micro-level data have been identified at all, they have not been

studied in relationship with laws on intellectual property rights (IPRs) and regulations on IP ownership (Geuna and Rossi, 2011), determining the university IP regimes and governance of university-industry technology transfer processes (Schoen et al, 2014).

This thesis describes case studies which examine four factors that can determine if, how- and to what extent- academic patents of university inventors contribute to the commercialisation of scientific knowledge and hence create socio-economic impact. This process of leveraging novel technologies and innovations- sometimes referred to as knowledge valorisation- is theoretically determined by *policy*, *institutional*, *organisational* and *individual* factors.

Where social scientific research shows that novel technologies can be shaped by societal needs and their transfer from university to the industry is often catalysed by exchange of knowledge (Arthur, 2009), one does not automatically know from which source they originated. In some cases it is clear that universities produced inventions and that 'academic' patents (Lissoni, 2012) can play a significant role. In order to boost this technology transfer some European governments implemented changes in their patent acts as part of *policy* changes (Janssens, 2005), while others implemented policy instruments with reimbursement schemes for academic patent applications (Enzing et al., 2004, Reis et al., 2003). Since the nineties of the last century most governments in the European Union (EU) have taken a number of institutional steps to enhance research commercialisation and technology transfer in their science and innovation policies (Geuna and Rossi, 2011) and ministries and science funding agencies prioritised the commercialisation of research within the context of the 'third mission' of universities² (OECD, 2013). Here, the organisation and role of university technology transfer offices (TTOs) is important for research commercialisation, facilitating e.g. contract research with companies, patent applications and the creation of spin-offs (Siegel et al., 2007). Other contributing factors to research commercialisation may also be associated with *individual*, psychosocial characteristics of scientists (Perkmann et al., 2013, D'Este and Perkmann, 2011).

Acknowledging the importance of research commercialisation to address societal needs, the potential use of patents as pathway for research commercialisation and taking identified knowledge gaps into consideration, there is an evident need to further examine how policy, institutional, organisational and individual factors can influence and determine the commercialisation of academic inventions, scientists' IP awareness, patent use and IP-based spin-off creation? **Section 1.2.** describes the research issues and objectives of this thesis. In line with these objectives a conceptual framework is drafted in **sections 1.3.** enabling the study of aligned research questions. Next, an in-depth literature review enables the development of a more sophisticated theoretical framework as described in **section 1.4**. Here, a novel taxonomy for knowledge valorisation ('Societal Impact Value Cycle') will be introduced. Finally, **section 1.5.** presents the thesis outline introducing case studies to be discussed in corresponding chapters.

² The first and second mission are: education and scientific research

1.2. Research issues and objectives

Business enterprises can appropriate and use their IPRs as 'legitimate tools and intangible assets' to monopolies domestic and foreign markets and prevent competitors to copy their technological innovations. This applies to companies of all sizes, e.g. multinational firms, large, small and medium sized enterprises (SMEs), as well as to university spin-offs or start-ups created by alumni and students. In very competitive, highly R&D intensive sectors (such as analytical instruments, chemicals, biopharmaceuticals and medical devices) early stage academic patents can play a substantial role in the process of technology transfer and the production pipeline of these companies (Delgado et al., 2013). IPR management is 'business as usual' for these companies, having stage gate processes in place to channel prospected successful projects into their 'industry road maps'. Research about the organisation of university-industry technology transfer processes have shown that academic patents can play a pivotal role filling the product pipeline of companies (Adams, 2014).

A reduction of companies' R&D budgets or the implementation of more open-innovation systems (Chesbrough, 2002) on the one hand, and limited funding for scientific research for universities on the other hand, often instigate increasing pressure towards public-privatepartnerships. These developments may result in a number of IPR related supply/demand problems and knowledge appropriation risks. First, cooperation with SMEs, which do not own patents or are not aware of the use of IPRs, might turn out to be troublesome for companies wanting to secure market opportunities (Bekkers et al., 2006). Second, collaboration with university staff might be cumbersome even in cases where scientists are IP aware, but appear not to be the legitimate IP owners or have different expectations about the value of their inventions (Gambardella et al., 2008; Tijssen, 2004). Third, although policy makers in many European countries have prioritised research commercialisation- including technology transfer with patents- they may not fully appreciate the potential 'conflicts of interests' -between companies and universities- regarding the strategic use and management of IPRs (OECD, 2013). In such situations, transparent IP ownership claims are a prerequisite for effective research commercialisation.

In line with these research issues and the knowledge gaps described in **section 1.1.** the research objectives of this thesis will be focussed on an analysis of:

- The socio-economic impact of academic patents aligned with science and innovation policies (at *societal level*), and
- Governance models of university TTO processes- implemented as a result of institutional and organisational policies- that have an effect on the output of academic patents and spin-offs (at *university level*) in the EU, and

• 'Psychosocial' characteristics of scientists determining their engagement with academic patenting and spin-off creation, hence contributing to job and patent value creation (at *individual* level)

1.3. Conceptual framework and research questions

The full array of patents and other IPRs can be used by companies to introduce their innovations into the marketplace (Greenhalg and Rogers, 2011) and to commercialise academic research at universities (Siegel et al., 2007). A patent application provides the patent applicant a legitimate tool to appropriate an invention. Next, the patented invention can be manufactured as products or be part of production process and become a crucial part of the intangible assets, monopolizing the exploitation of innovations for a maximum time period of 20 years in a country, designated by the patentee. Inventions are thus to be distinguished from innovations because patents are novel and not obvious technologies, while innovations are tangible new products, services and processes that have been introduced into the market place and have been bought by clients. In a knowledge-based economy, ownership and strategic management of IPRs allow companies to optimize the value of those intangible assets (McGinley, 2003). Patent citations have been in use to determine the innovativeness of firms in a specific sector (Harhoff et al., 1999) or a technology (Trajtenberg, 1990), by measuring the value of novel technologies (Hall et al., 2007) or through the market value of spin-offs aligned with the societal need (e.g. medical therapies).

Throughout this thesis, *academic patents* are defined as those university-invented patents, which comprise at least one tenured university scientist as inventor at the date of the filing of the patent application. In many technology transfer studies, no clear distinction has been made between university-held patents or university-invented patents which are assigned or transferred to or appropriated by firms. Both types of patents represent the total amount of academic patents, defined by the condition that at the time of the filing of the patent application at least one of the inventors has a position at a university (Lissoni, 2009 and 2012). Developed methods to quantify the number of academic patents (Lissoni, 2007) may not present a complete overview or cannot be used to measure the impact of an innovation policy instrument, targeted at a specific sector.

Through effective utilisation of academic patents it is possible to *create socio- economic impact*. University spin-offs exploiting academic patents are of paramount importance in the intermediate phases of the university-industry technology transfer process (Shane, 2001). The commercialisation of academic patents by companies and universities in the United States of America (USA) contributed to the production of significant numbers of new drugs and creation of jobs (McDevitt et al., 2014), a process where spin-offs played an important role. However, looking into the *institutional and organisational settings* at universities in the EU to boost research commercialisation, the size of scientists' engagement to become *personally* involved into patenting their research results and spin-off creation and commercialise academic research may be limited (Perkmann et al., 2013).

Acknowledging the vast body of literature on IP-based university-industry technology transfer in the USA, their long standing practice with academic patents and the implementation of university TTOs, the research described in this thesis focusses on the impact and effects of innovation policies on IP use and commercialisation at universities in the EU. The conceptual framework of this research in **figure 1.1**. shows how four factors can contribute to the utilisation of academic patents and their socio-economic impact. Here, four factors have to be distinguished: a) policy, b) institutional, c) organisation and d) individual factors. In line with this thesis' research objectives (**section 1.2**.) and comprehensive literature review above, this flow chart shows how these factors can interrelate (red coloured arrows) and contribute to the utilisation of academic patents (black coloured arrows), hence determining their socioeconomic impact. Although **section 1.4**. reviews the body of literature more in- depth, enabling the development of a more sophisticated theoretical framework, the conceptual framework in **figure 1.1**. suffices for the formulation of the overarching research question of this thesis: "How can academic patents create socio-economic impact? "

Figure 1.1. Factors a, b, c and d* contributing to the utilisation of academic patents and their socio-economic impact



* Black coloured arrows indicate unilateral relationship between this factor and the commercialisation of academic patents. Red coloured arrows indicate mutual relationships between the factors a, b, c and d.

Applying this conceptual framework to study the research objectives described in **section 1.2.**, following research questions will be addressed in this thesis:

a. How to identify and quantify academic patents, their use and socio-economic impact?

- *b.* How to measure the efficacy and impact of innovation policies to boost research commercialisation using patents, and if so, what is their impact?
- *c*. How to determine the relationships between the university IP regimes, their TTO governance models and their output in and use of patents and spin-offs?
- *d*. What are the personal drivers of scientists that motivate them to engage in various pathways of research commercialisation and how to associate them with their output?
- *e*. How to determine the value of academic patents and the value of university spin-offs that commercialise these patents?

Since patents are nationally registered after grant, enabling the patentee to exclude third parties to copy their patented technology within the country where the patent application has been granted, following parameters will be analysed to answer the research questions:

- a. Identification and quantification of academic patent applications and subsequent granted academic patents
- b. The transfer, assignment and licensing of academic patents to companies
- c. The utilisation of academic patents in a country, economic sector or technology
- d. Translation of used academic patents into innovations
- e. Socio-economic impact of academic patents

A methodology will be designed to identify and quantify academic patent at both national (e.g. Dutch universities in **chapter 2**) and international level (universities in EU countries in **chapters 4 and 5**). At both levels, a survey and interviews with stakeholders will enable the quantification of the utilisation of academic patents (*research question a*).

However, the impact of innovation policies and research funding on the utilisation of academic patents are confined to national countries, since such policies are designed by national policy makers. By this limiting conditions the impact of a science and innovation policy such as BioPartner in the Netherlands will be studied as a national case study (*research question b*). Interviews with stakeholders will be conducted to measure an increase scientists' IP awareness during the lifecycle of this innovation policy (**chapter 3**).

An international survey will be designed and sent directly to European scientists in all disciplines to acquire personal data on their engagement with patents and spin-offs, in relationship with their motivations to commercialise their research results, the governance model at their university TTO (**chapter 4**) and the IP regime of their university (**chapter 5**) (*research questions c and d*).

International Patent Classification codes for gene therapies will be used to quantify academic gene therapy patent applications, their utilisation and value (*research question e*). Patent
citations will be used to monitor their commercialisation during the maximum patent term of 20 years (**chapter 6**).

The research questions, applied methodologies to examine and answer these questions and the datasets that have been acquired and analysed during the research are summarized in **table 1.1**.

Table 1.1.	The analytical framework	with research questions,	, methodologies and data
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Research questions (a,b,c,d,e)	<i>Methodology</i> ^(*) (Input data from sub-projects)	Chapter
a.1) How to identify and quantify academic patents?	Matching data of academic inventors, with patents in patent databases using two algo (65, 000 scientists)	2 prithms
a.2) How to measure the use of academic patents and their socio-economic impact?	Surveys and interviews (50 questions and 230 companies)	
b.1) What is the efficacy and impact of innovation policies?	Matching academic biotechnology patents with companies from the BioPartner database in the Netherlands (90 companies)	3
b.2) How do the numbers of Dutch (academic) biotechnology patent applications increase in relationship with a policy instrument?	Use of biotechnology patent classification code Longitudinal, empirical biotech patent analysis	25
b.3) Increase of scientists' IP awareness?	Interviews with stakeholders (35 interviews)	
c.1) What are the relationships between the governance models of university TTOs and their output?c.2) What are the relationships between the appropriation of academic patents and university TTO governance models in the Netherlands?	Statistical non- parametric survey data analysi (four governance models) Longitudinal, empirical patent analysis	s 4
d.1) What are the relationships between university IP regimes and their output in patents and spin-offs?	Surveys and questionnaire (40 questions, 30 countries, 148 universities, 2, 665 scientists)	5
d.2) What are the associations between scientists' drivers and their output in patents and spin-offs?	Statistical non- parametric data analysis	
e.1) How to determine the value of spin-offs commercialise academic patents in the LSH sector?	Concordation of LS&H technologies into international patent classification codes (90, 000 patents)	6
e.2) What is the value of academic patents?	Analysis of the gene therapy patent landscape (93 patents)	
e.3.) How to determine the market capitalisation of a IP based university spin-off?	Patent citation analysis, combining patent data with annual reports, log curve fitting technique	1 25

(*) Openly accessible and commercial databases have been used (e.g. *Espacenet, Epoline PATSTAT, Epoque, WPI, Patentscope, Google Patent*)

1.4. Literature review supporting the conceptual and analytical frameworks

1.4.1 Patents and economic growth

Economic theories about technological innovations show that companies- with access to complementary assets, e.g. funds, manpower, and machinery- secure profits if they can benefit from a strong national IP regime, e.g. rules, regulations and legislation (Teece, 1993). In studies on per-capita GDP growth in 95 countries, positive correlations have been identified between countries' economic growth and IPR enforcement (Gould and Gruben, 1996; Rapp and Rozek, 1990). For IPR protection a measure of patent protection was used and associated with country scores in a range of values between 0 till 6- in which the value 0 represented a country without any IPR system at all, and value 6 represented a country with stringent IPR laws and litigation procedures (e.g. comparable to the USA).

Patents are frequently used as output indicators of companies' R&D processes and to measure countries' innovation performance (OECD, 2003). Patent portfolios of firms- operating in different sectors- have been regarded as one of their most valuable assets (Gambardella et al., 2008). Since patents represent the R&D strength research on high-tech companies showed that third party patent citations to patents in the portfolio of such companies have been used to indicate their market value (Hall et al., 2007, 2005) and the value of certain technologies (Trajtenberg, 1990; Narin et al., 1987). Because of necessary adjustment costs, companies that experience job growth show that their innovations might stimulate job creation (Greenan and Guellec, 2000). Those firms which have more patents to protect their innovations against competitors are likely to have lower adjustment costs, which eventually can result in the creation of more jobs (Meghir et al., 1996). Studies on R&D expenditures at manufacturing industries show that job-creating effects, in case of standard labour demand, augments with technology (Van Reenen, 1997). A significant correlation between technological innovations and employment growth was found in a survey in 37 developed countries where new jobs have been created at established firms (Won et al., 2005) which can grow through the exploiting of IPRs, e.g. licensing-out and cross-licensing (Andries and Faems, 2013).

Commercially interesting, novel results from scientific research at universities can be patented as 'academic inventions' (Van Looy et al., 2011), which in turn can be appropriated and developed by companies into innovations (Gulbrandsen and Slipersaeter, 2007; Meyer, 2003; Etzkowitz, 1998). Following the typology and taxonomy for university spin-offs these ventures can be defined as companies which have been created by scientists (Fryges and Wright, 2014; Rothaermel et al., 2007) and academic entrepreneurs, who are either former scientists or scientists who are still tenured at universities (Czarnitski et al., 2014). The performance of successful spin-offs can be associated with the sales and market value of innovative (patented) products (Hall et al., 2005; Di Gregorio and Shane, 2003). Also other factors than the exploitation of patents (Audretsch, 1995) can determine the growth and survival of spin- offs, e.g. capacity to attract capital (Wright et al., 2006), the characteristics of an entrepreneur towards risk aversion (Stam and Elfring, 2008), years of entrepreneurial experience (Hall et al., 2010; Pena, 2002) and networking capabilities (Walter et al., 2006).

1.4.2 Knowledge spillovers and innovations

Over the years, firms generally use three criteria and make deliberate choices to co-locate in geographic clusters: a) demand for specialised labor, b) development of intermediate goods and c) knowledge spillovers among the firms and knowledge providers in the supply chain (Marshall, 1920). The importance of 'knowledge spillovers' between universities and companies can be significant in case of industrial R&D (Grilliches, 1992). Researchers, who investigated technological change, emphasized the importance of proximity for effective knowledge and technology transfer (Audretsch, 1998; Feldman, 1994 and Acs, 1992). Proximity transforms knowledge into a sort of local public good thus generating localized knowledge spillovers. In fact, because tacit knowledge is the knowledge that (locally) spills over most frequently (Audretsch, 1998). The macroeconomic implication is that, by being colocalized, firms can reach higher numbers of successful innovations when located close to a source of knowledge. While this part of the body of literature explains why clustering is important for knowledge spillovers, it leaves the contribution of academic patents unspecified.

The propensity of firms to co-locate with a university is highest in knowledge-intensive sectors of industry, where also tacit knowledge plays an important role (Acs et al., 1992; Jaffe, 1989; Jaffe et al., 1993; Feldman and Florida, 1994). Many studies further explored the pioneering work of Jaffe (1989) presenting an estimation of a knowledge production function in a relationship between (proximate) academic research and the number of corporate patents in the USA (Grilliches, 1979). Analysing patents of co-localized companies cited in future patent applications showed that this localisation effect fades with time, but at a slow pace (Jaffe et al., 1993). This implies that the advantage of proximity decreases over time, allowing further dissemination of technologies e.g. as disclosed in patent documents. In line with this local knowledge spillover theory, scientists studied the propensity to innovate in geographical clusters and found that an innovation is more likely to occur when firms co-locate close to a university (Audretsch and Feldman, 1996). Contrary to the USA, these positive effects of knowledge spillovers on innovations have not been observed in European countries (Malerba and Breschi, 2001).

A prerequisite for any company to engage in knowledge spillover is the presence of 'absorptive capacity'. Potential stakeholders in public- private- partnerships need to master and own some critical parts of proprietary, technical subject matter in order to be allowed to embark on this partnership, or recognize their commercial value prior to absorb them into innovations (Cohen and Levinthal, 1990). Even then, markets of knowledge generation and technology transfer can show an asymmetry in supply and demand, e.g. when university researchers generate a large scientific knowledge base but there is no market demand for that knowledge at present (Acs et al., 1992). Here, one has to realise that results of scientific research have to be outstanding at the global level to ensure publications in highly ranked journals. Where economies can be of

regional scale, scientific developments including academic patents should be seen at hotspots on a global scale (e.g. the development of CRISPR- CAS 9)³.

1.4.3 The effects of innovation policies, IP laws and regulations on academic patenting

The long-term, socio-economic impact of innovation policies- enabling research commercialisation, using academic patents and spin-offs- has not been studied extensively (OECD, 2013, 2003; Arundel and Bordoy, 2002). Facing an economic crisis in the 1970s the US government decide to enact the Bayh-Dole legislation in 1980, ruling that a university can claim all IPRs forthcoming from government funded research (Henderson et al., 1999). At the same time, universities in the USA had to establish technology transfer and licensing offices (TLOs) enabling external companies and tenured scientists to engage in the process of commercialisation of their research findings. Empirical studies show the effects of the implementation of this new legislation in the USA with positive results from UCLA, Stanford and Colombia University in their patenting and licensing efforts (Henderson et al., 1999). Other studies showed that this new act was only one of the contributing factors in the rise of their patenting and licensing activities, while the increased amount of research funding for biomedical research has been the more important factor (Mowery et al., 2001).

Since the beginning of this millennium, most of the member states of the EU implemented Bayh-Dole like legislation, and many universities installed TTOs at central or decentralised level (Geuna and Rossi, 2011). In some European countries (e.g. Italy and Sweden with their professors' privilege) universities do not own IPRs on research results of their scientists (Janssens, 2005). The impact of changes of a national patent act away from 'professors' privileges' towards operational university-owned IP systems has been studied in Germany and Norway. After the reform of the national patent acts, German scientists, who held contacts with industries before the enactment of the new law, filed significantly less patents since 2002 (Czarnitski et al., 2015) while the number of university spin-offs in Norway decreased by 50% (Hvide and Jones, 2016).

Governmental policies on science and innovation may not only include the implementation of new IP laws, but also funding of scientific research including the organisation of research commercialisation (OECD, 2013). The implementation of these policies can affect the potential uptake of academic patents by spin-offs, which are geographically unevenly spread and may not possess counteracting powers against established companies with large IP portfolios (Beugelsdijk and Cornet, 2002).

³ A. Das (2018). CRISPR- CAS IP landscape

1.4.4 Organisation and governance of university technology transfer processes

Figure 1.2. shows how universities, companies and governments are the key actors involved in decision making processes determining the institutional and organisational aspects of research commercialisation e.g. transfer and utilisation of academic patents (Etzkowitz, 2008). In general, technology transfer and research commercialisation occur in a one-way direction from universities to companies (black coloured arrows), but policy development and the changes in the legal framework have their effects on all three actors involved in the process (red coloured arrows). On the one hand evidence-based data, showing direct relationships between innovation policies and research commercialisation with *academic patents that have been translated into innovations* are limited (Czarnitski et al., 2014; Arundel, 2013). On the other hand, the body of literature on university-industry technology transfer with academic patents, e.g. relationship IPR laws and academic patenting (Geuna and Rossi, 2011; Lissoni et al, 2009 and Janssens, 2005) and organisational factors at university level affecting technology transfer (Bekkers et al., 2006; Siegel et al., 2003), has grown considerably.

Figure 1.2. Key actors in processes of technology transfer and research commercialisation and their core business



TT = technology transfer, RC = research commercialisation

Most European universities established their TTOs -to support their scientists with contract research, creation of spin-off companies, filing of patent, applications or other IPRs- only recently (Geuna, 2011; Van Looy et al., 2011; Debackere and Veugelers, 2006). Compared technology transfer at universities in the USA, there is less empirical evidence on the scale and optimal processes of university–industry technology transfer of academic patents in Europe (Lissoni, 2013, 2012; Geuna, 2009). Some European studies examined the results of research commercialisation in relationship with IP rules and regulations (Geuna and Rossi, 2011), but US studies on university- technology transfer processes in public- private- partnerships of academia and industry, showed that IP policy alignment between involved parties was one of the key success factors contributing to research commercialisation (Siegel et al., 2007).

Contrary to the situation for scientists at universities in the USA, the legal, historical, social and cultural background at European universities may not always contribute to an optimal, active engagement of scientists in the commercialisation of their research (Janssens, 2005; OECD, 2003).

Policy makers often regard university TTOs as the primary driver for the commercialisation of research (OECD, 2013) and may not appreciate the important factor of scientists' engagement (discussed in **section 1.4.5**). The organisation of technology transfer processes using academic patents shows limited diversity in governance model types of university TTOs (Schoen et al., 2014; Geuna and Muscio, 2009). They described TTO governance models in terms of their internal organisation and logistics or by their location on campus (Link and Siegel, 2003). As a consequence, the impact of TTO governance models on the amount academic patents, subsequent transfer and commercialisation is unknown and the process of technology transfer may occur in sub-optimal conditions.

1.4.5 Scientists' engagement with research commercialisation, motivations and incentives

Assuming that scientists are IP aware (Pitkethly, 2012), familiar with the use of invention disclosure forms, will contact their TTO and that the university TTO has enough outreach capacity academic patents can be transferred or assigned to companies. Scientists and (future) academic entrepreneurs may not always possess the right skill set or required experience to engage successfully into research commercialisation (Zahra and Wright, 2011; Bertholt et al., 2010).

Applying the psycho-sociological theories of self-efficacy (Bandura, 1986) and planned behaviour (Ajzen, 1991), which both start at the level of individuals, scientists are independent decision makers. The theories of self-efficacy and planned behaviour show that knowledge, believes, intentions and personal traits determine the set of factors that determine people's behaviour. To this end, social- ecological models have been developed to further the understanding of dynamic interrelations among various personal intentions and their behaviour in the external environment, consisting of four systems (Bronfenbrenner, 1979). In their early years, parents, friends, family and neighborhood (*microsystem*) determine their confidence and trust. In a later stage, their development can be determined by mutual relationships in their immediate surroundings of the *mesosystem* (e.g. stimulating teacher, other pupils, the parents, workplace, school, peers, family networks) and can be either empowering or degrading.

The research in this thesis addresses the influences of the *exosystem*, which is the larger social system of a university and its ecosystem where a scientist works and is defined by community contexts like peers, deans, local politics and policies, research funding agencies, ministries and industry. Recent studies show that: a) recognition (societal impact, visibility), b) curiosity driven research (technology development, solving a puzzle) or c) entrepreneurship (business development and economic impact) are important drivers behind the individual engagement of scientists with research commercialisation (D' Este and Perkmann, 2011; Lam, 2010).

Considering the conceptual framework, both theories can be applied in order to examine how driving forces that motivate scientists will influence and explain their engagement with research commercialisation (Perkmann et al., 2013) using patents and spinning-off new business ventures. Finally, the *macrosystem* is composed of cultural values, customs and laws which refer to overall patterns of ideology and organisation which characterize a given society or social group.

Although research commercialisation has become a higher-priority objective for many universities in European countries, appropriate measures enabling scientists to commercialise their knowledge or research results have mainly been implemented at an organisational and/or institutional level (Arundel, 2013). Not much has happened at the individual level of scientists using incentives to report invention disclosures to TTOs or reward systems for scientists or special career trajectories (Panagopoulos and Carayannis, 2013; Friedman and Silberman, 2003). **Figure 1.3.** shows how previously discussed factors e.g. institutional, organizational and individual factors can influence whether scientists will engage in research commercialisation. At the output side the utilisation of academic patents, their contribution to technological innovations and job creation effect are shown as part of the socio-economic impact.

Figure 1.3. Factors that can infuence scientist's engagement with research commercialisation and their research impact



(Adapted from Perkmann et al., 2013 and Lam, 2010)

The creation and growth of IP-based spin-offs in an ecosystem around universities depend on a number of institutional, organisational and individual factors arranged at different levels (Bekkers et al., 2006). At national level, science and innovation policies and distinct IP characteristics of various sectors of industry are important (Siegel et al., 2007). At university level, the TTO capacity and university IP policy with regards to spin-off creation is important. At company level, IP management of spin-offs is important. Next to a university IP policy, the TTOs services to file patent applications and assist scientists with the creation of spin-offs are of prime importance (Shane, 2010).

Although scientists have expert knowledge in certain subject areas and might be engaged with the commercialisation of their research results, it requires both outstanding knowledge and ambitious entrepreneurship to accomplish a technology paradigm shift in a sector. The case of Sergey Brin and Larry Page is exemplary and unorthodox, as they developed their algorithm⁴ as an engine to search the internet during their PhD research at Stanford University. Soon after they started a 'garage' company funded by 'fools, friends and family' in Palo Alto in 1996, the company Google started its road to success. In this case, an interesting question remains whether such scientists and academic entrepreneurs 'to be' could have been assisted by their university TTO personnel in their adventure to become one of the most successful start-ups in the world, knowing that the first patent on this appropriate technology was filed by their university⁵.

Other successful business cases like the commercialisation of the rDNA technology by Genentech (Zucker et al., 2002, 1998) and PCR technology by Cetus (Adams, 2014) have contributed to an increased IP awareness amongst US scientists. Traditionally, scientists may have been more research- than entrepreneurship driven, thereby potentially destroying the granting of their patent applications due to novelty damaging publications or verbal disclosures by themselves, thus creating 'prior art' (Jones, 2013). Nowadays, scientists are more aware of the fact that patenting and publishing procedures can be aligned in time (Reed, 2013).

1.4.6 Identification, exploitation and value of patented academic inventions

The identification and quantification of academic patents can pose a number of problems, e.g. national legislation, ownership, kind of filings and involved TTO services (Lissoni, 2013, 2012, and 2009). If scientific research is financed in collaboration with- or contract research for companies, or by research funding organisations the parties involved can negotiate the assignment and appropriation of the patent (Geuna and Rossi, 2011). In that case, patents invented partially or fully by academic scientists and university staff, but filed by third parties as part of contractual agreements, may represent a blind spot since they cannot be identified easily. The KEINS database (Lissoni et al., 2008)- using patent applications filed at the European Patent Office is administrated by the EP- INV database at the Bocconi university in Italy- enables researchers to match these EP patent applications with the names of academic inventors.

The utilisation and exploitation of academic patents in (various) economic sectors may be measured by a variety of indicators, such as licensing (e.g. OECD, 2013) and patent citations by third parties (Hall et al., 2007). Licensing and patent citations indicators are frequently used to determine patent value (Harhoff et al., 1999; Hall et al., 2005). It is also used to estimate the

⁴ Brin S. (1999). Extracting Patterns and Relations from the World Wide Web. In: Atzeni P., Mendelzon A., Mecca G. (eds) The World Wide Web and Databases. WebDB 1998. Lecture Notes in Computer Science. Vol 1590, 172-183. Springer, Berlin, Heidelberg. https://doi.org/10.1007/10704656 11

⁵ US 6285999 B1 patent

additional employment effect of the exploitation of academic patents at spin-offs by applying the standard dynamic employment equation (Bogliacino and Vivarelli, 2012). This equation correlates employment growth over time with a number of variables (e.g. R&D expenditure) in the manufacturing (including pharma) and services sector in 15 countries in the EU. On the contrary, most university spin-offs without IP rights cannot secure profits and will hence be unable to develop as an important firm in the market place (Czarnitski et al., 2014). Academic patents in the USA contributed to the successful introduction of novel products and to job growth in the life sciences and health sector (McDevitt et al., 2014; Won et al., 2001; Shane, 2001). Direct relationships between the exploitation of academic patents and employment have been identified in European studies on university spin-off and academic entrepreneurship (Wright, 2014; Czarnitski, 2016).



Figure 1.4. Theoretical framework

After the literature review in previous sections 1.4.1 to 1.4.6, the conceptual framework can now be further developed into a more refined theoretical framework in **figure 1.4**, enabling a comprehensive study of the objectives and research questions of this thesis. The black coloured arrows in this figure present the architecture of possible interactions and relationships between determining factors: policies, research funding, institutional, organisational and individual- and hence the generation of academic patents. The *items in italics* represent sub-factors that can influence the *origin, appropriation, utilisation* of- and thereby the *socio- economic impact* from academic patents. In this framework, theoretically the maximum potential of innovations, jobs and value created through the utilisation of academic patents- as indicated with the red coloured arrows- can be achieved via: 1) their appropriation and commercial use by companies, 2) their licensing to and utilisation by spin-offs and 3) the creation of IP (patent)-based spin-offs by scientists themselves.

1.4.7 The position of patents in the 'Societal Impact Value Cycle'

Despite the role of the universities as 'engines for innovation' (Baumol, 2004), the creation of new scientific knowledge and insights is, in itself, not enough to address societal needs or achieve socio-economic impact (Van den Nieuwboer et al., 2015; Pronker, 2013; Audretsch and Keilbach, 2008). To derive these socio-economic benefits from scientific knowledge generated at universities, a process that transforms knowledge into valuable products and processes is in demand. In Belgium and the Netherlands this transformation process is called knowledge valorisation and these insights led to the design of the 'Societal Impact Value Cycle', in short the SIVC model⁶, synthesising recent scientific literature about 30 subprocesses of knowledge transfer and valorisation. This cyclic model presents a taxonomy of knowledge valorisation processes divided into 10 phases with 38 stages, going from unmet societal needs and articulating policy demands (U and A), towards the scoping and conducting of scientific research, shaping of opportunities (S, R and O), continuing with technology transfer (T), technical and commercial business development (D_T and D_C) and production (P) to markets and customer response (M and F) and so on and so forth (see Appendix). The many steps and activities involved in successful knowledge valorisation require competence and commitment of many different actors, e.g. scientists, technology transfer officers, firms and entrepreneurs and policymakers (Siegel and Wright, 2015). For all scientists and university staff, and especially those working at the faculties of science and engineering, academic patents play an important role during the stages of opportunity shaping **O**, technology transfer **T** and technical business development **D**_T.

This SIVC model fully describes 'knowledge valorisation' at universities in Belgium and the Netherlands which was defined as the composite result of knowledge or technology transfer, knowledge exploitation and academic entrepreneurship. The utilisation of academic patents on academic research can contribute during this valorisation process (KNAW, 2014).

⁶ Van de Burgwal, L., Van der Waal, M. and Claassen, E. (2018). Leveraging academic knowledge in the innovation ecosystem, *SMO*, ISBN: 978-90-69-267-5, <u>https://repub.jr.nl/pub/104386/</u>

1.5. Thesis outline

In line with the research objectives and questions (table 1.1), eleven sub-projects have been conducted between 2012 and 2017 to collect data enabling analyses to bridge the knowledge gaps (section 1.1.). Acknowledging that the pathways for utilisation of academic patents maybe non-linear, different for scientific disciplines and economic sectors several methodologies for data collection and statistical analyses have been applied.

Chapter 2 describes a novel methodology to identify and quantify academic patents followed by a survey to assess their use, exploitation, value and impact. After the collection of names of some 65, 000 university scientists in the Netherlands, who can potentially be mentioned as inventors in patents, two algorithms were used to match the names of these scientists with the names of inventors mentioned in patent applications of Dutch origin. Thus, some 2, 900 academic patent applications were identified in a time period of 10 years of which only 33% were university owned. Next, the commercialisation of granted, academic patents by companies in the Netherlands has been measured surveying the launch of new products, markets, financial values and employment growth.

Chapter 3 describes the impact of an innovation policy enabling the use of academic patents to stimulate the growth of the biotechnology sector. Here, the Dutch government implemented a <u>policy</u> instrument to support biotechnology companies by fuelling their product pipelines with academic patents based upon scientific research conducted at Dutch universities. Patent databases and biotechnology patent classification codes were applied to quantify the numbers of biotechnology patent applications during the lifecycle of this policy instrument and to measure the effect of other <u>institutional factors</u>. Thus a net 20% contribution of academic biotechnology patent applications to all biotechnology patent applications filed by Dutch organisations was quantified. Next, interviews with stakeholders were conducted to measure an increase of scientists' IP awareness over time.

Chapter 4 presents an analysis of a unique European IP dataset in order to identify and quantify relationships between university TTOs governance models and their IP output. These four types of governance models of TTOs (classical, autonomous, discipline-integrated and – specialised) are frequently found at universities in the EU and did not only affect the TTO output, but also the appropriation of academic patents by companies. Here, the <u>organisational</u> factors of TTOs and their relationships with the use and exploitation of academic patents have been examined. A country case study shows the impact of an innovation policy instrument that supported the implementation of TTOs (central vs. decentralised vs. regionalised offices) at universities in The Netherlands in 2004. The implementation of various governance models of TTOs can be associated with distinctive distribution patterns of the appropriation of academic patents by large firms, SMEs and university spin-offs.

Chapter 5 presents a scheme with new typologies for university IP regimes, followed by a pan-European survey which provided more insight whether the enactment of IPR laws and TTO IP ownership regulations led to more research commercialisation and patent filings. Contrary to frequently used approaches the survey was sent directly to individual scientists. This chapter describes the <u>individual</u> factors which motivate scientists to engage with research commercialisation and to file patents, plus the <u>institutional</u> factors in their (inter-) relationships with IP propensity, use and exploitation of academic patents. Institutionalised Technology Transfer models with obligatory contacts between scientists and TTOs can be associated with higher levels of academic patenting. The data further suggest that both the university IP regimes and the individual drivers of 2, 665 scientists working at 148 universities in 30 countries are significantly associated with academic patenting and spin-off creation. Here, scientists' motivations driving them to engage with research commercialisation and using patents were found to be far more important than the IP regimes of the universities where they work.

Chapter 6 describes a case study analysing which indicators can be used to determine the use and value of academic patents. In the globally operating economic sector of life sciences and health, both companies and universities appropriate large patent portfolios for different reasons. Studying the lifecycle of 93 gene therapy patents in an IP landscape, with more than 50 % university- invented- gene therapies, their exploitation from the priority filing dates till the maximum patent term of 20 years was analysed. Here, the numbers of patent licensees, the annual patent renewals and the numbers of third party patent citations to a particular patent application proved to be useful and significant indicators to assess the values of both academic patents. The last indicator also enables a quite accurate prediction of the market capitalisation of a university spin-off that exploited an academic gene therapy patent.

Chapter 7 summarises research findings, presents main conclusions and discusses their contributions to- or contrast with the body of literature. Some policy implications are presented plus a description of the fundamental research that did not yield enough representative data to provide conclusive answers to the questions and which therefore requires further research.

On the next page, **figure 1.5.** presents the thesis outline, indicating in which chapter the findings from the case studies, surveys and interviews, addressing research questions in relationship with examined factors a, b, c and d (that determine the utilisation of academic patents and subsequently their socio-economic impact), will be discussed.

Figure 1.5. Topical relationships in this thesis



* Black coloured arrows indicate unilateral relationship between this factor and the commercialisation of academic patents. Red coloured arrows represent interrelationships between the factors a, b, c and d.

Appendix



Phases and stages of knowledge valorisation in the Societal Impact Value Cycle:

U= Unmet (societal) needs assessment, A= Articulating (policy) demands, S= Scoping science, R= conducting Research, O= Opportunity shaping, T= Transfer of technology, D_T and D_C = technical and commercial Development, P= Production, M= Market deployment and F= Feedback.

⁷ Van de Burgwal, L., Van der Waal, M. and Claassen, E. (2018). Leveraging academic knowledge in the innovation ecosystem, *SMO*, ISBN: 978-90-69-267-5, <u>https://repub.eur.nl/pub/104386/</u>

Chapter **Z**

Academic inventions and patents in the Netherlands: a case study on business sector exploitation ⁸

Abstract

The identification of academic patents based upon scientific research and quantification of subsequent utilisation can pose a number of problems. Here, we describe a case study of the exploitation of academic patents in several sectors in The Netherlands, in which we quantify their commercialisation by domestic companies, including those managed by academic entrepreneurs. A novel, sophisticated semi-automated data collection methodology was adopted to identify all relevant university-invented patent applications that have been filed between 2000 and 2010. Personnel data of tenured university staff was matched with all patents applications from Dutch origin in the PATSTAT database of the European Patent Office, and a total of 2, 898 academic patent applications based upon scientific research at universities and related to university inventions were identified. For 952 of these university inventions, patent applications were filed by the universities themselves. The total number of university-based

⁸ This chapter was published as:

Van Dongen, P., Winnink, J. and Tijssen, R. (2014). Academic inventions and patents in the Netherlands: a case study on business sector exploitation, *World Patent Information*, (38), 27-32, <u>http://dx.doi.org/10.1016/j.wpi.2014.03.002</u>

The research methodology and data were presented during the annual EPIP conference at the European Commission, Bruxelles, September 2014, <u>http://www.epip.eu/epip2014</u>

related patent applications represent some five % of the total volume of patent applications of Dutch origin.

Subsequently, a representative survey among companies exploiting academic patents was carried out to gather information on the actual use of their IP, in terms of manpower involved in product or market development and estimated monetary value of the academic patents. Skewed and limited data about the effects of the exploitation of academic patents by large firms were excluded. We found that a variety of IP exploitation strategies has been used and that approximately 9,500 jobs were created by academic entrepreneurs in IP-based university spin-offs and start-ups in a time period of 10 years. Average revenues from these patents amounted to ϵ 42,000 per patent. Several findings from this national survey on the commercial exploitation of academic patents with regards to their use and monetary values, are in line with general results from the large-scale European studies, e.g. data from the PatVal and APE-INV surveys.

We conclude that: 1) it is possible to use the names of tenured scientists to identify academic patents and 2) the exploitation of academic patents by (spin-off) companies contributed to employment growth of high-tech jobs in various sectors of the economy.

2.1 Introduction

Nowadays, university researchers at industry-oriented 'entrepreneurial' universities can follow several pathways to interact and cooperate with (local) business companies (e.g. Perkman et al., 2013). University-industry linkages and commercialisation of university research may have significant impacts on industrial R&D (Cohen et al., 2002) and vice versa (Perkman and Walsh, 2009). Local, regional or national economies may benefit significantly from university knowledge transfer. Patents feature prominently as a mode of intellectual property ownership, vehicle for technology transfer and pathway for research commercialisation. 'Universityowned' patented technologies help create university spin-off companies managed by scientists, or start-ups by students or allumni where ownership of the patent is sometimes shared with coapplicants. Another group of patents representing university- generated intellectual property rights are often acquired, sold or licensed to companies for a variety of purposes. This group of 'university-research based' patents are filed in the name of or by companies and list the names of one or more university employed academics as inventors. Both types collectively are referred to as 'academic patents' (Lissoni, 2012). To analyse the latter-mentioned group of patent applications a sophisticated methodology has been developed. This chapter describes the methodology and the results.

Patents have proved to be a rich source of information for a vast body of empirical studies on university technology transfer, among others, university-industry R&D linkages, university inventors, science-based innovations, and the economic value of university research (e.g. Narin et al., 1997; Tijssen et al., 2000; Tijssen, 2002; Lissoni et al., 2008; Gamberdella et al., 2008). The PatVal-EU Survey was a large-scale comparative study on patent inventors across Europe, both public sector and private sector inventors (Giuri et al., 2007). Two recent review articles focus specifically on the various characteristics of academic inventors and their patents (Lissoni, 2012; 2013), where the empirical data were derived from the APE-INV study, which was concluded in 2013, covering six European countries (Denmark, France, Italy, Sweden, The Netherlands, and United Kingdom).

2.2. Background

Some universities in The Netherlands are, by European standards, very prolific in patenting. In part this is because of their scientific and technical research specialization profile, and partly because knowledge transfer and valorisation of scientific knowledge were added in 2005 to the main objectives and goals of all public sector universities. This 'third mission' is specifically meant to enhance the targeted dissemination of knowledge to user communities in the Netherlands - the business sector and industry in particular. Their knowledge transfer portfolio involves dedicated resources and efforts devoted to entrepreneurship courses, industry outreach programs, intellectual property right protection, transfer of university-developed technologies, commercialisation of university-IP through patent licensing and pre-seed funds to promote spin-off companies. All Dutch universities now run specialized organisational units- either a Technology Transfer Office (TTO) or a comparable unit- that engage in these activities. The

APE-INV study of European patent applications, relating to the years 2002-2006, identified some 600 academic inventors in the Netherlands who represented 2.75% of academic scientists employed by universities in 2005 to 2007 (Lissoni, 2012). This share is relatively low compared to the other five countries; double appointments and close ties between Philips, a large electronics company, and Eindhoven University of Technology are mentioned as possible explanations (Lissoni, 2012).

This research examines academic patenting at nine public research-intensive universities (out of 13 universities) and three university medical centers (out of eight medical centers): Delft University of Technology, Eindhoven University of Technology, Twente University, Wageningen University and Research Center, Leiden University, Free (VU) University of Amsterdam, University of Groningen, Utrecht University and Radboud University Nijmegen. The four university medical centers (out of eight medical centers) are those of Leiden University Medical Center, VU Medical Center at the Free University of Amsterdam, the University Medical Centre of Groningen and the Radboud University Medical Center.

The overall objective of this study was to ascertain the regional economic impacts of university IP. These findings have been reported elsewhere in a Dutch-language report for government policy-makers in the Netherlands (Van Dongen et al., 2013⁹). In this chapter, we focus on the methodology to identify and validate academic patents, and subsequent findings with regards to IP exploitation in the business sector and their assessment of the patent's financial value. The four research questions we addressed are:

- How can one reliably identify all academic patents where university research staff was actively involved?
- Does IP exploitation of academic patents, and their financial value for the company, differ by sector and by company size?
- How valid are the findings of this small-scale country-specific case study? More specifically, how do they relate to the results of earlier academic studies, especially the APE-INV study and PatVal-EU study?
- Does IP exploitation of academic patents contribute to employment growth?

2.3 Methodology and information sources

The first input for use in patent application searches that could be based upon scientific research is by the names of university staff members. So we had to identify and enter all full names of staff, including their scientific disciplines, who were employed by a university at some point during the years between 2000 and 2010 and who were active as a researcher in the natural sciences, engineering sciences, biotech, pharma or medical sciences. These data were collected in the first half of 2011 at the Netherlands Patent Office, after which the on-line

⁹ https://www.rvo.nl/IP based entrepreneurschip

databases the European Patent Office: Espacenet¹⁰ and PATSTAT database¹¹ have been accessed, searching for the names of the universities and their staff as applicant or inventor. Both sources enable large-scale automated searches for university presence in the patent documents at the level of entire countries or regions (e.g. Dornbusch et al., 2013). The first selection criterion we imposed is that patent applications are filed after January 1st 2000. We focus on patent applications since we are interested in Research and Development (R&D) activities and are less concerned with the legal issues of the patent granting procedures. The second selection criterion is that, at least for one of the inventors indicated The Netherlands (country code 'NL') as country of residence. Inventors for which the country is not, or incorrectly listed as NL, are not included. This type of error was deemed acceptable because patent families were used at a later stage in the patent selection process. Furthermore, patents usually have more than one inventor ensuring that the document would be included by a match on the name of one of the other inventors. We assume that using these sets of equivalent patent publications eliminated most of these errors. The final selection includes some 295 370 patent applications, thus considerably narrowing down search space for identification of university addresses and employees. Based on the lists of names of university employees as provided by the HR departments of the universities and medical centers a search list was constructed in which prefixes and postfixes of names were omitted. These truncated names were matched (partially) with inventor names using an n-gram matching algorithm (Kim and Shawe-Taylor, 1994) specifically designed to maximize the recall/precision rates by minimizing the numbers of false positives as well as false negatives (Appendix A).

For subsequent verification the sets of potentially relevant patent applications were sent to the TTOs of the participating universities and academic medical centers. The patent information pack for these manual checks included:

- title of the patent application;
- name(s) of the inventor(s) of a patent;
- name(s) of the applicant(s) for the patent;
- patent publication numbers of relevant patent applications, with the publication date for all publications belonging to a patent family;
- label to identify all patent applications that belong to a patent family, and
- number of patent applications, with the application date for all documents in a patent family.

Next, the TTOs and HRM departments matched these data to information on university staff names and affiliations, extracted from their information systems. The exemplary case of the appropriation and transfer of ownership, from a Delft University of Technology- invented patent assigned to Dutch company DHV b.v., shows why such a lengthy methodology is required (**Appendix B**).

¹⁰ <u>https://www.epo.org/espacenet</u>

¹¹ <u>http://www.epo.org/patstat.html</u> accessed between October 2011 and June 2012

The next question is how this IP patent pool based upon university research is used and exploited in the business sector? And, more specifically, how significant are the university IPbased spin-offs in terms of market-oriented exploitation of IPR - in terms of job creation and economic growth in regions around universities? To address these issues, 230 mail questionnaires were distributed by the TTOs of Dutch universities among companies within their client portfolios. This set of companies included university spin-offs and start-ups, as well as other small and medium sized companies located in the same region as the university, and some 30 larger enterprises, several of which are multinational companies headquartered in the Netherlands. For this case study we defined a region as the province where the university is located. For each of the patent applications that could be indisputably attributed, information was collected on their utilization history after the application date. The majority of the questionnaires were submitted to spin-offs and SMEs by the TTOs of participating universities while the remainder was sent separately, by the Netherlands Patent Office, to the IP departments at the headquarters of multinational enterprises. A total of 230 questionnaires were distributed with a final response rate of 34%. Data analysis of the returned questionnaires was done jointly by the TTOs and the Netherlands Patent Office, from September 2012 till January 2013. University-owned patents and university-research based patents were analysed collectively.

To assess the employment growth of IP-based university spin-offs in the IT and LSH sectors with academic entrepreneurs (AE), additional data have been acquired about e.g. the effect of funding, during a survey held in 2017 which addressed some 150 companies.

2.4. Results

2.4.1 IP-based outputs: patents and university spin-offs

Our study distinguishes two groups of patents. The first group consists of patent applications (co-) filed by the 'academic institution' itself (either a university or its university medical center) in which university staff is mentioned as inventor. The second group contains patent applications, to which university staff members contributed as inventor, that were filed by companies and for which the university is not mentioned as co-applicant. Approximately 66% of all university research-based patent applications in which university staff are listed as an inventor are registered by a company.

952 patent applications were filed by the nine universities- an average of 9.6 per university per year during the years 2000 - 2010, with a spread between 0 - 40 patent applications per university per year. Due to the 18 months duration of patent application processing before publication, the patent data for the year 2010 were incomplete at the time of this chapter. These patent applications were either filed at the Netherlands Patent Office, at the WIPO via the PCT procedure, or at the European Patent Office. The majority of patent applications was filed by either technical universities or general universities with large faculties of science. A total of 1, 946 patent applications based upon research at the nine universities (four technical and five

general universities) were filed by companies and other organisations. With regards to the latter, academics were also listed as inventors in patent applications that were filed by companies. We found an annual average of 19.7 patent applications with a university inventor per university per year during the years 2000 - 2010, with a spread between 1 - 80 patent applications per university per year. The largest numbers were filed for inventors working either at technical universities or universities with large faculties of science.

Hence, university research and academics employed by these nine universities and three medical centers contribute an annual average of 66 patent applications per 1,000 scientists. Universities have their own policies and strategies as to IP ownership and contractual arrangements - notably whether or not to build their own patent portfolio or to transfer patent rights to a third party (usually a company). Ownership of patents, or securing other commercially-valuable IP, is often essential for establishing university spin-off companies with successful products in the marketplace. We define IP-based spin-offs as "a business enterprise that applies IP-based knowledge, technologies or inventions that (at least partially) originate from university research". Spin-offs that were active in services sectors, such as architect studios and law firms, were excluded from our study. Prior research by the Netherlands Ministry of Economic Affairs (2003) indicated on average of 6.4 spin-offs was created per year. Our case study produces comparable results: an average of 6.7 spin-offs was created per year, 2.7 of which are based on university-filed patents.

2.4.2 Survey findings on commercialisation, exploitation and value of academic patents

To address the issue of IP exploitation and usage, a mail questionnaire was drafted and sent by the TTOs of participating Dutch universities to some 200 companies, while an additional 30 questionnaires were sent by the Netherlands Patent Office to the IP departments of five Dutch multinational companies.

In this socio-economic survey, university spin-offs (as micro companies) and small companies represent the bulk of the companies with an average of less than 10 employees. The micro companies had an average of 2.8 employees on January 1st 2011. Small companies (with 10-50 employees) had an average of 13.8 employees. The medium sized companies had an average of 110.5 employees. The R&D staff numbers are 2.5, 9.6 and 28.4 respectively.

In general, IP of academic origin often represents only a minor part of a company's entire patent portfolio. Overall, 71% of all companies, including all large companies, with more than 250 employees, owned non-academic patents. Company size is a defining factor: the share drops to 56% for the smallest companies, goes up to 75% for the small-medium companies, and to 91% for the medium-sized companies.

Table 2.1 describes the survey responses with regards to various types of patent utilization with companies. SMEs and large enterprises showed more variation than small companies. Where SMEs use university patents predominantly to showcase their innovative capacity and develop products, the large enterprises apply them for market development, to safeguard the exclusivity or to prevent others from applying for related patents. Many spin-off companies use a patent, or

a patent license (after the university patent application has been granted), to showcase their innovative capacity or to acquire external financing. There is an inverse relationship between company size and the likelihood that the patent emerged from joint R&D or contract research by the university. The majority of the patents, 60% on average, was used to develop innovations for the marketplace (question 3). A smaller fraction of the patents, still a significant 23 - 35%, was used for strategic objectives - either for blocking competitors or for securing markets (question 9). Some 10 - 20% of the patents was used for sublicensing or cross-

Company size	All	Micro	Small	Medium	Large
(number of employees)		(<10)	(10-50)	(51-250)	(>250)
(()	()	()
Survey questions:					
5 1					
1. Have you used the patent to demonstrate the	73	80	75	73	40
innovativeness of your company?					
2. Did the patent result from collaboration or	69	76	81	55	40
contract research with the university?					
3. Did you use the patent to develop a product,	60	61	75	64	30
set an industrial standard, or for another					
innovative application?					
4. Did you use the patent to acquire (additional)	54	71	56	9	30
funding?					
5. Did you incorporate the patent into a	47	44	56	64	30
portfolio of related patents?					
6. Did the patent help you develop a new	38	41	38	45	20
(niche) market?					
7. Did you use the patent for defensive	36	24	56	55	30
purposes?					
8. Did the patent help you acquire exclusivity in	35	41	38	18	20
the marketplace?					
9. Did you use the patent to prevent others from	28	24	31	45	20
denying you market access ?					
10. Did you use the patent to develop a (new)	27	22	44	18	30
process?					
11. Did you (sub)license the patent rights to a	18	20	13	27	10
third party?					
12. Did you use the patent for cross-licensing	8	10	0	18	0
negotiations ?					
Number of respondents (R)	78	41	16	11	10

Table 2.1. Utilisation of academic patents (percentage of all respondents per company size category with positive response)

licensing (questions 11 and 12). Although our study distinguishes an extra category of micro companies, our findings roughly correspond with the results of the PatVal-EU study of 7,556

patents, conducted among European countries, and based on the inventor's employer (Guiri et. al., 2007). We have used this category because many university IP-based spin-offs fit within the employee size of micro companies. In PatVal-EU study, depending on the company size ('small, 'medium', 'large') 50 - 65% of the company patents were applied for 'internal use', 10 - 22% for blocking competitors, 10 - 25% for (cross-) licensing, and 10 - 20% remained unused as 'sleeping patents' (Guiri et. al., 2007, p. 1119).

Choices for IP utilization and exploitation depend on various factors, notably an innovation's technological maturity and its commercial potential, closeness of the invention to marketintroduction, as well as the competitiveness of the underlying business model. The actual commercial relevance of the patents, as perceived by the IP-owning company itself, differs from their utilization and exploitation patterns displayed. **Table 2.2** shows that patents are most valued as an asset to gain exclusivity in the market place (point 1). Secondly, patents are held in high regard for corporate innovations - for developing a new product or a market. Interestingly, R&D collaboration with the university is not seen as a particularly relevant feature of a patent's value, especially by the large companies (see point 8). In contrast, small spin-off companies do value university collaborative partnerships, which is to be expected in view of the corporate background and science-based origin. It is also interesting to see that the micro and small companies value patents for financing. This outcome aligns with recent

Table 2.2.Commercial relevance of academic patents (average score on a low-high
scale from 1 – 7)

Company size		Micro	Small	Medium	Large
(number of employees)	All	(<10)	(10-50)	(51-250)	(>250)
Relevance of patent for:					
1. Exclusivity in the market place	6.21	6.25	5.80	7.00	6.50
2. Development of product or standard	5.83	5.74	5.70	6.29	6.00
3. Development of market	5.72	5.69	5.00	6.40	6.50
4. Financing	5.71	5.81	5.78	7.00	1.00
5. Patent portfolio	5.57	5.29	5.50	6.43	5.33
6. Prevent others from patenting	5.54	5.10	5.78	5.33	6.67
7. Prevent others from market access	5.21	4.29	5.20	6.00	6.50
8. Collaboration with university	5.21	5.67	4.80	5.33	2.67
9. Licenses to third parties	5.20	4.33	6.00	6.67	7.00
10. Development of process	5.15	4.75	5.00	6.00	6.00
11. Demonstrate innovativeness	5.14	4.93	5.42	5.80	5.00
12. Cross-licensing	4.75	3.50	No data	6.00	No data

findings by De Rassenfosse (2012) which indicate that companies of these sizes exhibit a much stronger reliance on these 'monetary patents' than large companies. That study also finds that European SMEs tend to use their patents more actively than larger firms, and generally have a

higher proportion of their IP portfolio that is out-licensed. However, the results of our case study suggest that medium-sized and larger companies in The Netherlands are the ones that tend to license-out IP to third parties.

The results in **Table 2.2** imply that companies were able to assess and score their patent-based IP by commercial value. How does one estimate that value? Two of the questions in our survey may have provided some support: a) time spent on the exploitation of academic patents for market and product development, and b) revenues generated so far. **Table 2.3** presents the aggregate findings on both questions. Significant differences occur between the company categories in as far as patented IP requires less than one man-year till commercial exploitation; while 30 - 40% of the smaller companies manage this within a year, this increases to between 60 - 70% for the larger companies (that have more resources for R& D). It is only among the smaller companies that IP was not used (yet) or the time spent on further development was unknown. Although most of the IP seems to have been used for various purposes, the overall majority of the patents have not generated any monetary revenues, partly because the IP was not intended for commercial use (save from blocking competitors or other non-monetary applications – see **Table 2.1**), partly because revenues are anticipated but have not materialized yet.

Table 2.3. Exploitation and valuation of academic patents (percentage of responses per company size category)

Company size (number of employees) How much time was spent within the company on further developing and exploiting an academic patent?	All	Micro (<10)	Small (10-50)	Medium (51-250)	Large (>250)
		1.0	-		
None	5	10	0	0	0
< 1 man-year	42	32	38	73	60
1-4 man-years	27	34	25	0	30
> 4 man-years	22	24	19	27	10
Unknown	4	0	19	0	0
What are the revenues so far directly from an academ	ic patent	?			
None	62	61	81	36	60
<€ 30 000	6	10	0	9	0
€ 30 000 - 100 000	9	5	13	18	10
€ 100 000 - 1 000 000	8	15	0	0	0
>€1 000 000	12	2	6	36	30
Unknown	4	7	0	0	0

Fifty eight per cent of the micro companies and forty three per cent of the small companies invested at least one man-year in various forms of patent-based IP exploitation, especially on product development and marketing. Statistical data on man-year investments were used to generate a national-level evidence-supported estimation of the job volumes resulting from IP generated by university research. This calculation applies only to university spin-offs licensingin academic patents and IP based spin-offs but excludes the possible employment effects at small, medium and large companies. On average, some 2.7 IP-based university spin-offs have been launched per institute per year (see section 2.4.1). This kind of spin-offs in the Netherlands has on average some 10 employees within five years after their launch and their survival rate is rather high, and stable, at a level of 70%¹². In addition to these IP-based spinoffs, approximately the same number of R&D based companies were established. Taking also into account the total number of university spin-offs and the number of knowledge institutes (universities, university medical centers, practical universities and (university) research institutes) in The Netherlands, the estimated number of jobs created between 2000 and 2010 amounts to approximately 9,500 in regions surrounding universities. These numbers are in line with facts and figures provided in (annual) reports by business incubators and science parks at Dutch universities (Yes!Delft, 2010; Stichting Kennispark, 2011; LeidenBioSciencepark, Biggar Economics, 2011). These reports also mention 'multiplier effects' showing that one full time equivalent (FTE) of employees at a micro company contributes to more employment in the region, approximately an additional FTE.

The micro (university spin-offs) earned approximately \in 40, 000 euro of business related to their patents during the first five years. In comparison, the average revenue across all companies is less than \in 200, 000 per licensed patent. The average revenue per patent amounts to \in 42, 000. Revenues between \in 100, 000 and \in 1, 000, 000 only occur within amongst the smallest companies. 'Blockbuster' revenues, of \in 1, 000, 000 or more, were found in all company categories. Within the sub-set of 35 patents with known non-zero revenues, these large-earners represent a 35% share. This fraction is similar to the findings in the Europe-wide PatVal-EU findings, where 32% falls within this estimated income class (Giuiri et al. 2007; p. 1121). Interestingly in the PatVal-EU study, these estimates were provided by the inventors themselves some 6-7 years after the filing of the patent application, when asked for the minimum price at which the patent's owner would have sold the IP rights on the day on which the patent was granted.

2.5 Limitations

We are convinced that our data collection methodology was able to identify the vast majority of all academic patents produced by the selected universities and university medical centers. How many patents were missed remains unknown, but based upon cross checks with data available at some university TTOs, we expect less than 5%. Our approach, applying a combination of

¹² Personal communication A. Groen, Netherlands Institute for Knowledge Intensive Entrepreneurship (NIKOS), Twente University, 2013

sophisticated data mining of patent databases and manual data verification, proved to be extremely labor-intensive. Semi-automated matching of inventor names to academic staff was cumbersome and problematic- partly as a result of lack of standardization of names in the patent documents, partially because of the reluctance of university HRM departments to share confidential information on staff members. Future studies of this kind would benefit from higher-quality address information on inventors mentioned in patent applications within patent databases, or improved administration records by TTOs and universities made accessible through a public register of academic inventors of the kind now partially developed within the APE-INV project (Lissoni, 2013).

2.6. Conclusions

Our survey of the companies that appropriated academic patents within the Netherlands produced new insights into the exploitation of those patents, their employment effects and estimated financial value for companies. Although the sample size was relatively small (78 respondents) the general patterns we observed within the survey data, broken down in categories by company size, provided relevant information on if and how the IP is used within the Dutch business sector. As expected, significant differences occur between the micro companies, mainly university spin-off, and the larger companies which also included multinational companies. Here, it is important to emphasize that, due to non-response of large companies, we could only quantify the IP-based employment effects of university spin-offs, which proved to be reliable and representative. The survey stratification by company size was essential to obtain a richer and more balanced view of the variety with IP application strategies and the distribution of patents according to their monetary value for a company. Several of the findings with regard to patent usage and their values align closely with general patterns observed within prior large-scale surveys among thousands of patents across Europe.

Given the relevance of this kind of IP-based information for evidence-based debates on the effectiveness of academic knowledge transfer initiatives and on government policies with regard to science and innovation, we strongly advocate further national or regional case studies on this topic, preferably with the framework of follow-up research programs at the European or global level.

Appendix A Applied algorithms for the identification of academic patent applications

Using a *fuzzy matching algorithm* enables the identification, quantification and further selection of patent documents for each university. For this fuzzy matching several of the following search strings consisting of initials, first names, and surnames were generated and used;

<initial(s)> surname; surname <, initial(s)> ; <first name(s)> surname; surname < first name(s)>

For individuals (usually female employees) who also carry the name of their partner additional variants were generated:

<initial(s)> maiden name ; maiden name <, initial(s)> ; <first name(s)> maiden name ; maiden name <, first name(s)> ; <initial(s)> maiden name ; surname-maiden name <, initial(s)> ; <first name(s)-maiden name ; surname-maiden name <first name(s)>

The *n-gram algorithm with* n=4 is used to compare the name variants with the names of inventors of the documents included in the document set. The algorithm splits the various strings into pieces of, in this case by means of a sliding window, a window size of 4 characters proved to give satisfactory and reliable results in general. All the 'text chunks' that are generated for the names of the employees of a university are compared with the names of the inventors of a patent application. The percentage of matching 'text chunks' is used as an indicator of equality of the two strings (Kim and Shawe-Taylor, 1994). As tolerance criterion at first, 70% was used. This criterion was set based on experiments where the number of wrong identifications, false positives, was low and also that the matched names were indeed very similar. A manual check done at one of the participating universities resulted in lowering this tolerance level to 50%. This lower tolerance percentage has the disadvantage that more 'false positives' are included in the results. This is not seen as a serious disadvantage as manual 'validation' is part of the procedure.

However, this algorithm did not work correctly for short character strings with inventors that have surnames with less than 5 characters, and hence we can miss relevant patent applications. To overcome this drawback an extra matching test was done using exact comparison for names of up to 5 characters. The results of the previous stages in the selection process were used to identify all relevant patent families. All publications of the relevant patent family were retrieved and duplicate occurrences of similar names was prevented.

Appendix B

Title

Original patent priority document Priority patent filing date NL patent registration

Academic invention Granted in EP procedure *Patent applicant* **Inventors** Patent classification class

Transfer of ownership Year of transfer Method for treatment of waste water with sludge granules NL1021466 (C2) 16 September 2002 18 March 2004

WO 2004/024638 A1 17 December 2008 Delft University of Technology Marc van Loosdrecht, Merle de Kreuk C02F3/12

Assigned to DHV bv. (<u>EP1542932 B2</u>) 2005

NB.

The patent documents on the next pages show the appropriation of academic patents, demonstrating the transfer of ownership and assignment of this Delft University of Technology- invented patent to a Dutch engineering company DHV b.v.

1		Bureau voor de Industriële Eigendom Nederland	① 1021466
	and the second s	ື	DCTROOI ²⁰
6	Aanvrage om octrooi Ingediend: 16.09.20	i: 1021466 02	(1) Int.Cl. ⁷ C02F3/12, C02F3/26
. @	Ingeschreven: 18.03.2004		(73) Octrooihouder(s): Technische Universiteit Delft te Delft.
(Dagtekening: 18.03.2004		(72) Uitvinder(s): Marinus Cornelis Maria van Loosdrecht te De Lier Maria Kriste de Kreuk te Gouda
e	03.05.2004 I.E. 2004	4/05	 (7) Gemachtigde: Drs. A. Kupecz c.s. te 1000 HB Amsterdam.
6) Werkwijze voor het	t behandelen van afvalwate	
	(7) De uitvinding heeft b	betrekking op een werkwijze v	r.
	nutriënt bevat. Volge	ens de uitvinding wordt het af	voor het behandelen van afvalwater dat een te verwijderen
	na het toevoeren va	n het te behandelen afvalwat	valwater in een eerste stap aan slibkorrels toegevoerd, word
	een zuurstof-omvatti	end gas worden gefluïdiseerd	er in een tweede stap de slibkorrels in aanwezigheid van
	kunnen bezinken. Al	Idus kunnen niet alleen doelm	d, en in een derde stap de slibkorrels in een bezinkstap
	tueel ook stikstofver	bindingen en fosfaat.	natig een organische nutriënt worden verwijderd, doch even-
	De uitvinding heeft b	petrekking op een werkwijze t	r.
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	na het toevoeren va	n het te behandelen afvalwat	valwater in een eerste stap aan slibkorrels toegevoerd, word
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	tueel ook stikstofver	bindingen en fosfaat.	natig een organische nutriënt worden verwijderd, doch even-
6	De uitvinding heeft b	betrekking op een werkwijze	r.
	nutriënt bevat. Volge	ens de uitvinding wordt het af	voor het behandelen van afvalwater dat een te verwijderen
	na het toevoeren va	n het te behandelen afvalwat	valwater in een eerste stap aan slibkorrels toegevoerd, word
	een zuurstol-onwatt	end gas worden gefluidiseerd	er in een tweede stap de slibkorrels in aanwezigheid van
	kunnen bezinken. Al	Idus kunnen niet alleen doelm	d, en in een derde stap de slibkorrels in een bezinkstap
	tueel ook stikstofver	bindingen en fosfaat.	natig een organische nutriënt worden verwijderd, doch even-
	De uitvinding heeft t	betrekking op een werkwijze to	r.
	nutriënt bevat. Volge	ens de uitvinding wordt het af	voor het behandelen van afvalwater dat een te verwijderen
	na het toevoern va	n het te behandelen afvalwat	valwater in een eerste stap aan slibkorrels toegevoerd, word
	een zuurstof-omvatt	end gas worden gefluidiseerd	er in een tweede stap de slibkorrels in aanwezigheid van
	kunnen bezinken. Al	Idus kunnen niet alleen doelm	4, en in een derde stap de slibkorrels in een bezinkstap
	tueel ook stikstofver	bindingen en fosfaat.	natig een organische nutriënt worden verwijderd, doch even-
	De uitvinding heeft b	eatrekking op een werkwijze t	r.
	nutriënt bevat. Volge	ens de uitvinding wordt het af	voor het behandelen van afvalwater dat een te verwijderen
	na het toevoeren va	en het te behandelen afvalwat	valwater in een eerste stap aan slibkorrels toegevoerd, word
	een zuurstof-omvatt	end gas worden gefluidiseerd	er in een tweede stap de slibkorrels in aanwezigheid van
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	tueel ook stikstofver	bindingen en fosfaat.	natig een organische nutriënt worden verwijderd, doch even-
	De uitvinding heeft b	betrekking op een werkwijze	r.
	nutriënt bevat. Volge	ens de uitvinding wordt het af	voor het behandelen van afvalwater dat een te verwijderen
	na het toevoeren va	n het te behandelen afvalwat	valwater in een eerste stap aan slibkorrels toegevoerd, word
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	tueet ook stikstofver	bindingen en fosfaat.	natig een organische nutriënt worden verwijderd, doch even-
	De uitvinding heeft t	betrekking op een werkwijze t	r.
	nutriënt bevat. Volge	ens de uitvinding wordt het af	voor het behandelen van afvalwater dat een te verwijderen
	na het toevoeren va	n het te behandelen afvalwat	valwater in een eerste stap aan slibkorrels toegevoerd, word
	een zuurstof-omvatt	end gas worden gefluidiseerd	er in een tweede stap de slibkorrels in aanwezigheid van
	kunnen bezinken. Al	Idus kunnen niet alleen doeln	3, en in een derde stap de slibkorrels in een bezinkstap
	tueel ook stikstofver	bindingen en fosfaat.	natig een organische nutriënt worden verwijderd, doch even-
8	De uitvinding heeft b	petrekking op een werkwijze t	r.
	nutriënt bevat. Volge	ens de uitvinding wordt het af	voor het behandelen van afvalwater dat een te verwijderen
	na het toevoeren va	n het te behandelen afvalwat	valwater in een eerste stap aan slibkorrels toegevoerd, word
	een zuurstof-omvatt	end gas worden gefluidiseerd	er in een tweede stap de slibkorrels in aanwezigheid van
	kunnen bezinken. Al	Idus kunnen niet alleen doeln	6, en in een derde stap de slibkorrels in een bezinkstap
	tueel ook stikstofver	bindingen en fosfaat.	natig een organische nutriënt worden verwijderd, doch even-
021466	De uitvinding heeft t	betrekking op een werkwijze t	r.
	nutriënt bevat. Volge	ens de uitvinding wordt het af	voor het behandelen van afvalwater dat een te verwijderen
	na het toevoern va	n het te behandelen afvalwat	valwater in een eerste stap aan slibkorrels toegevoerd, word
	een zuurstof-omvatt	end gas worden gefluidiseerd	er in een tweede stap de slibkorrels in aanwezigheid van
	kunnen bezinken. Al	Idus kunnen niet alleen doein	d, en in een derde stap de slibkorrels in een bezinkstap
	tueel ook stikstofver	bindingen en fosfaat.	natig een organische nutriënt worden verwijderd, doch even-

(19)	Furopairches Patentamt Suropaen Furopaen	
	Office surapéen des brevets	(11) EP 1 542 932 B1
(12)	EUROPEAN PATER	NT SPECIFICATION
(45)	Date of publication and mention of the grant of the patent: 17.12.2008 Bulletin 2008/51	(51) Int CI.: C02F 3/12 (2006.01) C02F 3/26 (2006.01) C02F 3/26 (2006.01)
(21)	Application number: 03751604.4	(86) International application number: PCT/NL2003/000642
(22)	Date of filing: 16.09.2003	(87) International publication number: WO 2004/024638 (25.03.2004 Gazette 2004/13)
(54)	METHOD FOR THE TREATMENT OF WASTE VERFAHREN ZUR ABWASSERBEHANDLUNG PROCEDE DE TRAITEMENT D'EAUX USEES	WATER WITH SLUDGE GRANULES MIT SCHLAMMPARTIKEL PAR DES GRANULES DE BOUE
(84)	Designated Contracting States: AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IT LI LU MC NL PT RO SE SI SK TR	DANGCONG P ET AL: "Aerobic granular sludge- a case report" WATER RESEARCH, ELSEVIER SCIENCE PUBLISHERS, AMSTERDAM, NL, vol. 22 pag. 5 Echurger (1909, (1909, 1909, 1909, 1909, 1909))
(30)	Priority: 16.09.2002 NL 1021466	33, no. 3, Pebruary 1999 (1999-02), pages 890-893, XP004151609 ISSN: 0043-1354 • MORGENBOTH E ET AL : "Aerobic granular
(43)	Date of publication of application: 22.06.2005 Bulletin 2005/25	sludge in a sequencing batch reactor" WATER RESEARCH, ELSEVIER SCIENCE PUBLISHERS, AMSTERDAM NL vol 31 no 12 1 December
(73)	Proprietor: DHV B.V. 3813 EX Amersfoort (NL)	1997 (1997-12-01), pages 3191-3194, XP004098442 ISSN: 0043-1354
(72)	Inventors: VAN LOOSDRECHT, Marinus, Cornelis, Maria NL-2678 HL De Lier (NL) DE KREUK, Merle, Krista NL-2806 EM Gouda (NL)	SLUDGE SEQUENCING BATCH AIRLIFT REACTOR* BIOTECHNOLOGY AND BIOENGINEERING. INCLUDING: SYMPOSIUM BIOTECHNOLOGY IN ENERGY PRODUCTION AND CONSERVATION, JOHN WILEY & SONS.
(74)	Representative: Kupecz, Arpad Octroolbureau Los en Stigter B.V. P.O. Box 20052 1000 HB Amsterdam (NL)	NEW YOHK, US, vol. /5, no. 1, 5 October 2001 (2001-10-05), pages 82-92, XP001124872 ISSN: 0006-3592 • PATENT ABSTRACTS OF JAPAN vol.018, no. 176 (C-1183), 25 March 1994 (1994-03-25) & JP 05 337492 A (MITSUBISHI KAKOKI KAISHA LTD). 21
(56)	References cited: EP-A- 0 776 864 WO-A-03/070649	December 1993 (1993-12-21)
	BEUN J J ET AL: "Aerobic granulation in a sequencing batch airlift reactor" WATER RESEARCH, ELSEVIER SCIENCE PUBLISHERS, AMSTERDAM, NL, vol. 36, no. 3, February 2002 (2002-02), pages 702-712, XP004312290 ISSN: 0043-1354	The file contains technical information submitted after the application was filed and not included in this specification

I Note: Within nine months of the publication of the mention of the grant of the European patent in the European Patent Bulletin, any person may give notice to the European Patent Office of opposition to that patent, in accordance with the Implementing Regulations. Notice of opposition shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

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Chapter 3

Policies and patenting to stimulate the biotechnology sector: Evidence from the Netherlands ¹³

Abstract

Evidence-based results of science and innovation policies stimulating the use of academic patents and contributing to the development of economic sectors are scarce. This chapter describes the effects of a national policy instrument to commercialise scientific research during the emerging stage of the biotechnology sector (i.e. BioPartner programme in the Netherlands). This instrument provided funding for the reimbursement of biotechnology patent applications and assistance for the creation of spin-off companies. We studied general trends in biotechnology patent applications in the time period between 1990 and 2009 and quantified the appropriation of academic biotechnology patents by industry. Biotechnology patent classification codes and databases of the European Patent Organisation were used to define and quantify all Dutch biotechnology patent applications.

Matching the data from these applications with the names of some 65, 000 Dutch potential academic inventors and 3, 400 Dutch academic patents, we found a net contribution of the

¹³ This chapter was published as:

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policy instrument of some 20% of all Dutch biotechnology patent applications. However, we did not observe that this policy instrument contributed to an increase of the overall number of biotechnology patent applications in the sector. Our data suggest that the 'business culture using biotechnology patents' and IP awareness amongst scientists at universities have improved.

3.1. Introduction

3.1.1. General

Patents are often used as one of the output indicators to measure the output of scientific research and can make major contributions to future innovations (OECD, 2013; Tijssen, 2011, 2001). The impact of policies on patenting for the commercialisation of scientific knowledge can depend on national patent rules and regulations (Geuna and Rossi, 2011), effectiveness of university-industry technology transfer (Siegel et al., 2007) and other elements of innovation systems (Etzkowitz, 2008). Quantitative data about the effects of policies on technology transfer (TT) including the exploitation of patents are scarce or limited to a specific sector for a short period of time (Chatterjee and Rohrbaugh, 2014). Policies regulating public funding of biotechnology research were found to be only one of the many factors that positively affected the strength of the biotechnology industry (Senker, et al., 2000). A comparison between dedicated biotechnology instruments in public policies and general policy instruments in 14 EU member states showed that the first category of instruments did not contribute to better country commercialisation performance (Enzing, et al., 2004). An EU wide study indicated a lack of internationally comparable and suitable quantitative and qualitative input and output data describing the performance of biotechnology innovation systems (Reiss et al., 2003).

Annually, the biopharmaceutical sector invests billions of euros into medicine development with an average duration of R&D projects of twelve years (Pronker et al., 2011). In this competitive sector, patents are crucial to secure investments and R&D collaborations for the development of the pipelines of companies, thus enabling product development (Fernald et al., 2014). After the enactment of the Bayh-Dole act in the United States, some 150 medicines based upon university patents were approved by the FDA (McDevitt et al., 2014). The birth and growth of the biotechnology sector in the United States started with the successful exploitation of university patents by a number of spin-off companies (Zucker, Darby and Brewer, 1998), but the long term effects of the impact of policies on and the appropriation and use of university patents at the emergent state of the biotechnology sector have not been studied empirically (Patzelt and Brenner, 2008). With this research, we wish to bridge this knowledge gap and contribute to existing literature by testing hypotheses about whether policies and patenting have contributed to the development of the biotechnology sector. We studied the effects of the BioPartner programme in the Netherlands and this chapter addresses following research questions:

- Can we identify academic biotechnology patent applications?
- Can we quantify the contribution of this policy instrument and measure the appropriation of academic biotechnology patent applications by companies in the sector?
- Does such a dedicated policy instrument lead to a sustainable 'business culture using biotechnology patents' at universities, and
- Can we ascertain whether the developments in the number of academic biotechnology patent applications would not have occurred without a dedicated policy instrument?

3.1.2. The innovation system and the biotechnology sector in the Netherlands

Here we refer to an assessment of the OECD of the innovation system and give a short description of the biotechnology sector. The high quality of scientific research and the high rate of patenting were regarded as positive features of the innovation system (OECD, 2005). On the contrary, the low level of private R&D, the less than optimal interaction between industry and academia, the insufficient innovative entrepreneurial activity and the limited ability for research commercialisation were described as negative features. Before 2000, the role and position of universities as serious actors in the innovation system in the Netherlands was relatively weak. The budgets from the Ministry of Education, Culture and Science (MECS) did not provide funding for research commercialisation, technology transfer or spin-off development. The Ministry of Economic Affairs (MEA) used a number of instruments to enhance the growth in the number of start-ups and university spin-offs.

In the 90s of the last century multinational corporations (e.g. DSM, Unilever, Nutricia, AkzoOrganon, Solvay, Abbott and Philips) dominated the biotechnology sector in the Netherlands, while some small and medium sized-enterprises (e.g. RijksZwaan, Nunhems, Pacques, Norit) played an important role in the sectors of plant breeding and environmental technology (Van der Giessen, 2014). Most Dutch companies are operational in three subsectors (i.c. medical, food and industrial biotechnology). Given the potential contribution of \notin 595 billion from the life sciences and health (LSH) sector to the GDP in the Netherlands (European Commission, 2002), this sector has been earmarked as a top sector by the government since 1998. At that time, entrepreneurship in the life sciences and health sector in general and at universities in particular was poorly developed (Enzing et al., 2004).

To improve this situation, the government decided to implement a policy instrument to stimulate the growth of this sector This policy instrument contained the BioPartner programme with the objective of commercialising academic knowledge through the creation of 75 new life science companies and stimulating a more 'entrepreneurial business culture' at universities (MEA, 2000). The first stage grant of this programme (some 25% of the total budget of \in 45 million) provided salaries for university biotechnology scientists and funding for the reimbursement of biotechnology patent applications (up to \in 250.000, with a maximum of 2.5 years) to consortia of companies and universities. Between 2000 and 2004, the BioPartner organisation also facilitated further support for the utilisation of academic life science research (e.g. master classes, business plan development, access to finance, incubator programmes, use of equipment).

3.2. Theory and hypotheses

With the invention of recombinant DNA technology in the 70s, modern biotechnology has become an enabling technology in many industrial processes in the sectors like chemistry, nutrition, pharma and plant breeding (Zucker et al., 1998). In these sectors, the number of biotechnology patent applications have been used as one of the indicators to measure the average commercial country performance, including the Netherlands (Enzing et al., 2004). In

light of the objectives of the BioPartner programme, we focus our research on the transfer or appropriation of academic patents from the original academic inventor to a company. **Figure 3.1** shows how research funding enables the commercialisation of in the life sciences research following a pathway from discovery, to an invention disclosure at a technology transfer office (TTO) followed by the filing, licensing or sales of academic biotechnology patents. The blue coloured arrows, circles and boxes in this figure emphasize the additional funding by the BioParttner programme, enabled by the MECS, and its objective to create spin-offs.

Figure 3.1. Research funding in the Netherlands^(*) and transfer of academic biotechnology patents^(**)



(*) Research funding by 1) MECS = Ministry of Education, Culture and Science; 2) MEA = Ministry of Economic Affairs; 3) BioPartner programme

(**) Adapted from Panagopoulos and Carayannis, 2013; Van Looy et al., 2011; Geuna and Rossi, 2011; Friedman and Silberman, 2003

We define academic biotechnology patent applications as those applications in which at least one of the inventors has a university position at the date of the filing (Lissoni, 2012) and is working in the discipline of biotechnology or life sciences. The Netherlands Patent Act does not provide for a "professor's privilege". Therefore, patent applications based upon publically funded academic research are proprietary assets of a university (Lissoni et al., 2009). Academic (biotechnology) patent applications can be filed or appropriated by universities (Lissoni, 2013), licensed or assigned to alumni start-ups (Åstebro et al., 2012) or university spin-offs (Lehoux et al., 2014), companies and technology institutes (Andries and Faems, 2013; Pugatch et al., 2012).

'Scientists' patent awareness' has been defined as the phenomenon that scientists are informed about the possibility to use patents for technology transfer (Nerkar and Shane, 2003) and 'a business culture using biotechnology patents' as scientists' motivation to file a patent application in order to commercialise their research (Di Gregorio and Shane, 2003). Scientists
may either contact their university TTO, a research funding organisation or a third party during the decisionmaking process for the filing of a patent application.

In the Netherlands, the financial budgets for scientific research as proposed by the MECS and the MEA have to be approved by the government and will then be administrated via research funding agencies, such as the Royal Dutch Academy for Arts and Sciences (KNAW) and the Netherlands Research Council (NWO). Some of the commercially viable results of academic research at the faculties of science, engineering and medicine might eventually lead to patentable inventions (Van Dongen et al., 2017b). Within the framework of **figure 3.1**, we examine the relationships between the research funding by BioPartner on the filings of academic biotechnology patent applications by: a) university spin-offs, or their appropriation into the biotechnology patent portfolio of b) companies or c) technology institutes (all indicated in red colour). The linear flow model of technology transfer in this framework oversimplifies a more complex reality, because public-private-partnerships between university scientists and the business sector might influence the intellectual property (IP) output.

Between 2000 and 2004, the BioPartner programme provided financing to consortia of universities and companies in order to reimburse the costs for filing biotechnology patent applications. Therefore, we use this feature of this policy instrument as a measure of technology transfer in life science research. The time required to translate scientific results into patentable technologies differs per discipline and economic sector. For patents in the biotechnology sector we take six years as the default time span (OECD, 2007). The year 2000 has been chosen as a dividing line since biotechnology patent applications filed after that year can be correlated with the start of the BioPartner programme. We have to distinguish four categories of patent applications in this research:

- 1. All biotechnology patent applications filed by Dutch organisations (companies, universities, etc.)
- 2. Academic biotechnology patent applications funded by the BioPartner programme
- 3. Academic biotechnology patent applications not funded by the BioPartner programme
- 4. Academic patent applications in all disciplines and sectors (as a control)

Research commercialisation can be measured by the transfer of academic patents to companies via a TTO (Siegel, Veugelers and Wright, 2007), so we formulate following hypothesis HI.a: The BioPartner programme will contribute to a significant, additionally increase in the number of academic biotechnology patent applications filed by- or licensed to Dutch biotechnology companies. Hereto, we will quantify the number of all biotechnology patent applications filed (1), subsequently the number of academic biotechnology patent applications funded by Biopartner (2). Hypothesis 1.a will be accepted if the number of applications (2) contribute to an increase of more than 5% in the number of all biotechnology patent applications filed (1). In line with literature about the relationships between academic patenting, spin-off creation and academic entrepreneurship (Lehoux et al., 2014; Lissoni, 2013 and Lissoni et al., 2009; Shane, 2004) we hypothesise that HI.b: the BioPartner programme will contribute to a significant number of academic biotechnology patent applications filed after the year 2000. Hypothesis 1.b will be accepted if more than 50 % of the spin-offs which

received research funding during the programme has filed biotechnology patent applications reimbursed by BioPartner. Referring to effects of changes in patent laws on university patenting (Geuna and Rossi, 2011; Mowery et al., 2001) and literature on the commercialisation of biotechnology research by 'star scientists' in spin-offs (Di Gregorio and Shane, 2003; Nerkar and Shane, 2003; Zucker, Darby and Amstrong, 2002), we hypothesise that *H2*: the BioPartner programme will contribute to an increased 'patent awareness' amongst scientists (Pithkely, 2012) and a sustainable 'business culture using biotechnology patents' at universities. This hypothesis will be accepted if more than 50% of biotechnology scientists engaged as entrepreneurs in spin-offs who university TTOs and received research funding, display knowledge of the patent system, e.g. functions, procedures and costs.

A number of governments in the EU, including the Netherlands, have introduced policies for research commercialisation, e.g. incubators in the ecosystems around universities in the last decade (OECD, 2013; Fini et al., 2011). At the same time, university boards have given more priority to research commercialisation and patenting (van Looij et al., 2011) and non-monetary incentives for scientists stimulating them to disclose their inventions at university TTOs have become more common (Panagopoulos and Carayannis, 2013). Considering these other policy developments, we expect that *H3*: the numbers of Dutch academic biotechnology patent applications filed after the year 2000 may have to be corrected, as these numbers could also be correlated with other factors than the BioPartner programme. This hypothesis will be accepted if statistical analyses show that the R^2 for annual academic biotechnology patent applications is much larger than the R^2 for annual academic patent applications in all disciplines.

3.3. Methodology and data resources

To quantify the patent-related contribution of the BioPartner programme to the Dutch biotechnology sector, we identified the four categories of patent applications described in the previous section. Applications are the filings for which applicants have decided to request a patent from the patent granting organisations. They are a direct measure of the explicit interest of innovating companies and other organisations to assert their patent rights on the biotechnology market. Filings can be regarded as a preliminary patent application activity indicating the potential interest of innovating organisations from all over the world in the biotechnology market. The data collection was carried out with PATSTAT – the worldwide statistical database¹⁴ of the European Patent Office (EPO). The analysis for this study was conducted by using the International and Cooperative Patent Classification codes for biotechnology patents¹⁵ (**Appendix**) to identify and quantify the numbers of all Dutch biotechnology patent applications with a Dutch origin (companies, universities, spin-offs, inventors, etc.). The time period that we investigated ranged from 1995 till 2009.

¹⁴ PATSTAT, <u>http://www.epo.org/searching-for-patents/business/patstat</u>

¹⁵ EPO (2011). Definitions of patent classifications, <u>http://www.epo.org/searching</u>

Next, we used a methodology adopted from the Fraunhofer Institute (Dornbusch et al., 2013) to identify all academic patent applications, including biotechnology applications. With the assistance of human resource departments of universities and available personnel data from the databases of the KNAW¹⁶ we collected the first names, surnames and scientific disciplines of some 65,280 scientists with employment contracts at Dutch universities between 1990 and 2009. We matched the names of these tenured scientists working at Dutch universities with the names of inventors mentioned in patent applications and used two algorithms to control for homology effects, using a methodology as described in chapter 2 (van Dongen, Winnink and Tijssen, 2014). All identified academic patent applications can then be combined with the biotechnology patent classification codes (**Appendix**) to yield the relevant academic biotechnology patent applications. Our study thus considers all national and international biotechnology patent applications at the EPO (=EP) and the World Intellectual Property Organisation (under the Patent Cooperation Treaty at the WIPO (=PCT)).

Subsequently, all academic biotechnology patent applications have been categorised by their university of origin of the invention and the patent applicant. As biotechnology patent applicants, Dutch universities, technology institutes, domestic multinational firms and SMEs, university spin-offs, individual inventors and foreign organisations (with headquarters outside of the Netherlands) have been taken into consideration.

Finally, all identified academic biotechnology patent applications were matched again with the names of existing Dutch dedicated biotechnology companies and also with the names of the new university spin-offs which had been created with the assistance of the BioPartner programme¹⁷. To analyse the data, the following software and databases were used: Espacenet, Epoque, PATSTAT, Google (Patents and Scholar). Between 2013 and 2016, we conducted 35 semi-structured interviews with research funding organisations, university TTO personnel at ten universities, BioPartner spin-offs, SMEs and large (multinational) companies in the Dutch biotechnology sector. During these interviews, both quantitative and qualitative data were collected to validate our findings about the appropriation, ownership, licensing and exploitation of academic biotechnology patents.

3.4. Results

3.4.1. Overall numbers of biotechnology patent applications

Key findings from a longitudinal analysis of (academic) biotechnology patent applications filed between 1990 and 2009 are shown in figures 3.2, 3.3 and 3.4. **Figure 3.2** shows the development of the overall numbers of NL, EP and PCT biotechnology patent applications filed by Dutch organisations. In this time period, the overall number of unique, biotechnology patent applications filed by Dutch organisations increased, but we observe a decrease in the years between 2000 and 2004 when the BioPartner programme was operational. In this period,

¹⁶ KNAW, <u>https://dans.knaw.nl</u>

¹⁷ Innotact (2005). <u>http://www.BioPartner.nl</u> (page 65, 66 and 67)

a total number of 1,785 biotechnology patent applications were filed by Dutch organisations (companies, universities, etc.). More than 200 biotechnology patent applications were filed based upon academic research that took place at the universities involved in this study (see **section 3.5 on the limitations**). In the subsectors of medical (red) biotechnology, Akzo Nobel and Crucell were important patent applicants, while DSM and Unilever were important applicants in industrial (white) biotechnology, and Syngenta, Wageningen University and the Wageningen Research Foundation were important patent applicants in the green, agricultural sector and in food biotechnology.

Figure 3.2. Overall numbers of biotechnology patent applications filed by Dutch organisations



 Table 3.1.
 Top 10 Dutch biotechnology patent applicants ^(a)

Organisations	Patent applications (2000)	Organisations	Patent applications (2009)
1.DSM	48	1.Philips	81
2.AKZO Nobel	39	2.DSM	72
3.Crucell	26	3.Unilever	37
4.Unilever	21	4.Crucell	36
5.DLO ^(b)	16	5.Synthon	24
6.Leiden university incl. Medical Center	13	6.TNO ^(b)	24
7.TNO ^(b)	12	7.Syngenta	19
8. Utrecht university incl. Medical Center	10	8. Leiden university incl. Medical Centre	18
9.Wageningen University	9	9. University Utrecht incl. Medical Centre	11
10.Syngenta	4	10. Wageningen University	10

^(a) There is a potential overlap in numbers of patent applications due to classification in more than one patent classification code and filing via multiple application procedures ^(b) Wageningen Research Foundation (DLO) and Netherlands Organisation for Applied Scientific Research (TNO)

Table 3.1 shows comparative data in numbers of biotechnology patent applications filed by the top ten Dutch organisations via national or international application procedures (NL or EP and PCT, using the European Patent Convention or the Patent Cooperation Treaty).

The BioPartner programme contributed to the start of some 90 university life science spinoffs¹⁸ and provided funding to file 337 biotechnology patent applications by 92 companies in the period between 2000 and 2004 (figure 3.3.a). These 337 biotechnology patent applications represent a significant contribution of 19% of the total number of biotechnology patent applications, while some 80% of these applications were filed by Dutch companies that were already operational in the biotechnology sector before 2000. After the process of matching the names of tenured university scientists with the names of the inventors in the 337 biotechnology patent applications financed by the first stage grant of the BioPartner programme, we found that only 24 of the 90 new university spin-offs- which received support from BioPartner- had filed 47 academic biotechnology patent applications (14 %). Ten spin-off companies, operational in the life sciences sector before the start of BioPartner in 2000 (e.g. Crucell, Pamgene, Pepscan, Keygene), filed another 22 BioPartner funded biotechnology patent applications during the programme (6%). We observe that the BioPartner programme contributed to 337/1, 785= 19% of all biotechnology patent applications filed by Dutch organisations, while 47/1, 785=3% was filed by 24 new university spin-offs starting in the years when this programme was operational (figure 3.3.b). In figures 3.3. a and b the red coloured pies represent the number of patent applications that were filed by spin-offs which were already operational prior to the start of the programme. In line with the objectives of the BioPartner programme, 47 patent applications have been appropriated by spin-offs assisted during this programme. Although we have been able to quantify the size of the contribution of BioPartner funded patent applications to the biotechnology sector, this effect is quite small compared to the number of patent applications which have not received funding from the





A. BioPartner funded patent applications to firms and SMEs (15%) B. Idem, patent applications to spin-offs (3%)C. Non- BioPartner funded patent applications filed by thirdparties (81%)

¹⁸ Innotact (2005). <u>http://www.BioPartner.nl</u>

programme. Hence, we reject *H1.a. and H1.b*, stating that the BioPartner policy instrument would contribute significantly to an increase in the number of academic biotechnology patent applications filed by companies (1.a) and spin-offs (1.b), thus contributing to research commercialisation in the biotechnology sector.

3.4.2. BioPartner's effect on the filings of academic biotechnology patent applications

A quantitative analysis shows that some hundred Dutch companies, universities and technology institutes filed approximately 3, 450 academic patent applications between the years 2000 and 2009, out of which 565 were classified as biotechnology patent applications. In a general comparison between the number of academic biotechnology patent applications filed by universities, technology institutes and companies prior to (1990-99) and since the start (2000-2009) of the BioPartner programme, we found an overall increase of 26 %. **Table 3.2** shows that since the year 2000, 266/565 = 47 % of all academic biotechnology patent applications have been filed by Dutch companies (including university spin-offs). Here, we find that Dutch universities filed almost four times as many biotechnology patent applications in the time period between 2000-2009 compared with the time period between 1990-1999.

Table 3.2.	Numbers	of a	cademic	biotechnology	patent	applications	categorised	by
	applicants	s and	time peri	iod				

	1990 - 1999	2000 - 2009	Change rate (%)
Patent applicants	(=A)	(=B)	(= B/A)
Dutch universities	45	176	+ 391
Dutch technology institutes (*)	49	61	+ 124
Domestic companies (including university spin-offs)	247	266	+ 107
Foreign companies (with headquarters outside of The Netherlands)	108	62	-57
Total	449	565	+ 26

(*) Netherlands Organisation for Applied Scientific Research (TNO) and Wageningen Research Foundation (DLO)

A statistical analysis of the patent data- as projected in **figure 3.4-** shows a small, but significant, increase in the numbers of annual academic biotechnology patent applications between the years 1990-2009, with a slump in the time period between 2000 and 2004. Taking into consideration that the total numbers of all Dutch biotechnology patent applications decreased (**figure 3.2**), whereas the academic biotechnology patent applications increased during the BioPartner programme and continued to increase after its closure, we have to validate these findings, e.g. during interviews with TTO staff and entrepreneurs in university

spin-offs (section 4.3). In summary, we found that the potential commercialisation of academic research in the biotechnology sector within the national boundaries of the Netherlands, enabled by the use of academic biotechnology patent applications, increased significantly.





(*) Significant at level p= 0.05

3.4.3. Origin, appropriation and use of academic biotechnology patent applications

Sections 3.4.1. and 3.4.2 described the effects of the BioPartner programme on the numbers of biotechnology patent applications and the transfer of academic biotechnology patent applications to companies in the Dutch biotechnology sector. A policy instrument like the BioPartner programme might also have an additional effect on the origin of academic biotechnology patent applications and technology transfer distribution patterns to organisations in the biotechnology sector (e.g. domestic companies, academic biotechnology patent applications). Figure 3.5 shows the numbers of the academic biotechnology patent applications that have been filed before (1990–99, blue coloured histograms) and since the start of the BioPartner programme (2000-2009, red coloured histograms). In this figure the numbers

Figure 3.5. Numbers of academic biotechnology patent applications, categorised by their university of origin, before (1990-1999) and since the start of the BioPartner programme (2000-2009)



N (1990–1999) = 449 and N (2000-2009) = 565

of the applications have been categorised in relationship with the name of the university of origin (defined as the university where the research has taken place on the basis of which the biotechnology invention has been patented). Since the start of the BioPartner programme in 2000, it is clear that all universities, except the Free (VU) University Amsterdam and University Twente contributed to more academic biotechnology patent applications. At the same time, we notice that- the scientists at- the universities and medical centres of Leiden (e.g. G.J. van Ommen) and Utrecht (e.g. J.G.J. van de Winkel) were involved in more than fifty per cent of the academic biotechnology patent applications. We could not quantify reliable patent data from the universities and medical centers in Rotterdam, Amsterdam, Groningen and Maastricht.





Most important applicants of academic biotechnology patent applications Figure 3.6.b from 2000- 2009, since the start of the BioPartner programme



PAs = patent applications

Figures 3.6.a and 3.6.b show the changes in the distribution of academic biotechnology patent applications by their applicants in a time period between 1990 - 2009. Combining these changes in distribution data with the results presented in the last column of **table 3.2**, we found three major developments in the filing and appropriation of academic biotechnology patent applications that occurred since the year 2000: a) an *increase* of 63% by Dutch multinational corporations (e.g. Philips, Akzo, DSM, Unilever and Nutricia), b) an *increase* of 150% by university spin-offs (especially at the universities Leiden, Utrecht and Nijmegen), and c) a *decrease* of 57% by foreign companies (defined as companies with headquarters located outside The Netherlands). In turn, this increased patent awareness plus the higher level of services from personnel of the growing university technology transfer offices might have led to higher levels of filing and appropriation of academic biotechnology patent applications by universities. A different contributing factor could be that the collaboration between universities and companies in the biotechnology sector was stimulated by top sector policies and public-private-partnerships¹⁹.

The Technology Foundation STW is a division of the Netherlands Research Council which is responsible for the funding of scientific research at universities. STW applies a policy to file patent applications in case companies in the so-called STW user committees have expressed their interest in the commercialisation of the research results. From a legal point of view, these patent applications have been filed by and therefore belong to STW, but they should be

Figure 3.7. Biotechnology patent applications filed by Dutch universities and STW (*) before (1990-1999) and since the start of the BioPartner programme (2000- 2009)



(*) STW = Technology Foundation STW (a Dutch research funding organisation)

¹⁹ Top Consortia Knowledge and Innovation (2016). <u>https://www.topsectoren.nl</u>

considered as a result of scientific research which has been place at universities, usually conducted by PhD students. STW's policy implies that within a certain amount of time either the university or the company will become the legitimate owner of the patent²⁰. **Figure 3.7** shows the number of academic biotechnology patent applications that the universities and STW filed between 1990 and 2009. Here, we found large differences in the number of applications, which can be explained by the patent policies of universities and STW. For example, the Leiden university filed and appropriated most patent applications as a result of the fact that their technology transfer office applies an intellectual property ownership and licensing policy comparable with most of the universities in the USA. More than 60% of the 'Leiden' biotechnology patent applications -once granted- were licensed as research tools to companies or used in public–private-partnerships²¹.

Since the universities of Leiden and Utrecht had filed most of these academic biotechnology patent applications, we found it interesting to compare the differences of their patent policies in relationship to spin-off support and the impact on the number of spin-offs. Eight university spin-offs appropriated biotechnology patent applications based upon research at Leiden University vs. 19 spin-offs which appropriated patent applications based upon research at Utrecht University²². Nowadays, the patent policies of most universities allow them either to file patent applications as a co-applicant with industrial partners or to encourage the latter to do so as sole applicant (KNAW, 2014). In either situation, academic inventors are entitled to be mentioned in the mentioned in a patent application.

We collected and analysed data from thirty five interviews with Dutch companies, research funding organisations and university TTOs to measure the impact and validate the quantitative results of the BioPartner programme. The interviews were semi-structured, took about 30 minutes to one hour and were conducted on location or by telephone. Interviewees could give four possible answers to each question stating that: a) they agree (positive response), b) they disagree (negative response), c) the question is not appropriate for my organisation (N.A) or d) they have no answer. Table 3.3 shows the percentages of positive responses by all interviewees of different categories of organisations, when asked about the use of academic biotechnology patents enabled by the BioPartner programme and the effects of this programme. E.g. if only one interviewee of the eighteen interviewed university spin-off companies responded positively to a question we noted this response with a score of six per cent. Where SMEs use academic biotechnology patents to demonstrate their innovative capacity and develop products, the large companies apply them both for market development and protection. Many spin-offs use a patent, or a patent license (after the academic patent application has been granted), to show their innovative capacity and to acquire extra funding. On the other hand, university TTOs use biotechnology patents to demonstrate the innovative capacity and to license them to third parties. The responses from research funding organisations, university TTOs, spin-offs and companies to question 8 confirm the general outlook that BioPartner has stimulated the filing of patent applications. Although two categories of respondents did not answer the questions 9 and

²⁰ Idsardi, Technology Foundation STW, personal communication, 2015

²¹ Smailes, LURIS, Leiden University, personal communication on university IP policy, 2014

²² Fallaux, Utrecht University, personal communication, 2014

10, we observe that according to research funding organisations, university TTOs and spin-offs, the patent awareness amongst scientists has increased, while 50% of the TTOs and almost 80% of the spin-offs acknowledged that they noticed that over the years universities have become more business minded using biotechnology patents. From data in **figure 3.3.b** in section 4.1, we know that 24 of the 90 spin-offs which started between 2000 and 2004, received financial support from BioPartner when filing (47 academic) biotechnology patent applications. Based on our quantitative patent (**figures 3.4., 3.5. and 3.7.**) and survey data (**table 3.3**), we accept *H2*, which stated that BioPartner will contribute to an increased 'patent awareness' amongst scientists and a sustainable 'business culture using biotechnology patents' at universities.

Table 3.3.Relative importance of the use of academic biotechnology patents,
categorised per type and size of organisation (percentage of interviewees
with positive responses)

Organisations Questions	Research funding organisation	University TTO	University spin-off company	SME	Multinational/ large company
1.Did you use the patent to develop a new (niche) market?	N.A.	N.A.	6	20	25
2. Idem 1, to develop a product or process?	N.A.	N.A.	11	40	25
3. Idem 1, to protect your market?	N.A.	N.A.	N.A.	20	50
4. Idem 1, for a (sub-)license to a third party?	N.A.	50	17	20	25
5. Idem 1, to demonstrate the innovative capacity of your organisation?	N.A.	67	67	80	50
6. Idem 1, for extra funding e.g. investors?	N.A.	N.A.	50	40	No answer
7. Idem 1, for cooperation with other parties?	N.A.	17	22	20	25
8. Did Biopartner stimulate the filing of patent applications?	100	100	72	20	50
9. Did BioPartner enduce 'patent awareness' amongst scientists?	100	67	83	No answer	No answer
10. Did BioPartner contribute to a 'business culture using patents' at universities?	No answer	50	78	No answer	25
Number of interviews per type of organisation	2	6	18	5	4

N = 35 N.A. = not appropriate

Finally, **figure 3.8** shows the increase in the number of academic patent applications in all disciplines (APAs) and academic biotechnology patent applications (ABPAs) that were filed in the time period between the 1990 and 2009. A statistical analysis of these data shows that the numbers of both kinds of patent applications increased significantly and that the numbers of annual academic patent applications in all disciplines had increased more than the numbers of annual academic biotechnology patent applications. The data in this figure also show that the contribution of the number of academic biotechnology patent applications to the number of academic patent applications is substantial at 28% annually and varies between 15-44% per year. Considering that the R^2 for annual academic patent applications in all disciplines, we see no reason to apply

corrections for the measured effects of the BioPartner programme in the previous sections with regards to academic patenting. Given the multitude of possible relationships between policies, research funding, collaborative research with the industry, scientists' patent awareness and other factors with academic patent applications, such corrections would have been necessary if the patenting results in **figure 3.8** would have shown that the increase in numbers of academic biotechnology patent applications (and the R^2 of this increase) would have been much larger than the increase in numbers of all academic patent applications in all scientific disciplines.

Figure 3.8. Numbers of academic patent applications (APAs*) and academic biotechnology patent applications (ABPAs *) in The Netherlands



(*) APAs and ABPAs significant at p=0.05

Looking at the data in **figure 3.6.a and 3.6.b** on the number of university spin-offs that appropriated academic biotechnology patent applications, we observed an overall growth of some (8% of 565) / (7% of 449) = 144% in the time period between 1990 and 2009. However, due to lack of available data on spin-off companies in other sectors and the data from **figure 3.8**, we cannot examine whether the appropriation of academic biotechnology patents by university spin-offs in the biotechnology sector remained at a comparable level with all academic patent applications by spin-offs in all sectors. Therefore, we cannot prove *H3* stating that the number of Dutch academic patent applications filed since 2000 has to be corrected, as that can also be attributed to other policy factors than the BioPartner programme.

3.5. Limitations

We have focussed on the filings and appropriation routes of academic biotechnology patent applications in order to demonstrate the effects of the BioPartner programme, as a policy instrument to enhance the commercialisation of scientific research in the life sciences by companies in the Netherlands. The quantitative part of this research was carried out between 2012-2017 and comprises the data from the universities of Delft, Eindhoven, Twente, Wageningen, Groningen, Leiden, Nijmegen, Utrecht and the Free University (= VU) University Amsterdam only, including four faculties of medicine or university medical centres in the Netherlands. Although our heuristic survey was limited, interview data with fifteen IP managers at companies, research funding organisations, university TTOs and with twenty life science entrepreneurs in spin-offs between 2013 and 2016 enabled us to validate our findings.

For the methodology in this research two assumptions are critical: a) On the basis of interviews with professors and technology transfer office managers, we estimate that in more than 95 % of all academic patent applications the names of (assistant/associate) professors are included as one of the inventors, and b) the number of (assistant/associate) professors in the scientific disciplines where patentable research results might be expected (i.e. engineering, natural sciences, medicine) remained at a stable level of some 15, 000 full time equivalents between 1990–2009 (Chiang Mera, 2015). Whether or not the records regarding tenured scientists per university were complete depend on the accuracy of the human resource databases of the universities and medical centres included in the study.

3.6. Conclusions and discussion

Our research shows that:

- a. Between the years 1995 and 2000 the number of biotechnology patent applications of Dutch organisations has increased and has been at a more or less stable level since then;
- b. The BioPartner policy instrument enabled the appropriation of academic biotechnology patent applications by companies at a level of approximately 20% of all Dutch biotechnology patent applications during the five years that the programme was operational, and
- c. 'Scientists' patent awareness' and 'business culture using biotechnology patents' at universities increased, which can be positively associated with the BioPartner programme.

Patenting has increased sharply over the last decades as industries shifted more and more from manufacturing towards knowledge-based high-tech production. In the biotechnology sector, this growth has been even more pronounced as can be witnessed at the major patent granting offices in the USA and Europe (Pugatch et al., 2014). According to international data about the number of the Dutch biotechnology patent applications filed at the European Patent Organisation, the Netherlands occupies a fifth position globally (Lawrence, 2007). In this research we observed a spectacular increase of biotechnology patent applications, while their before the start of the BioPartner programme is in line with global biotechnology patenting rates (Barone, 2005). We have been able to provide empirical evidence about the filings, appropriation, transfer and use of academic biotechnology patent applications in the Netherlands over time and the contributions of the BioPartner programme in this matter.

The observed growth in number of academic biotechnology patent applications in the Netherlands between 1990 and 2009 is in line with the growth observed at universities in Europe (OECD, 2012; Lissoni, 2013), but the percentage of university-owned biotechnology patents in the Netherlands is higher than at universities elsewhere in Europe (Lissoni et al.,

2012). The 14% appropriation of academic biotechnology patent applications by foreign companies and universities is within the common ranges of appropriation and attrition by multinational corporations (Arora, Belenzon and Patacconi, 2015). This percentage also shows that the contribution of Dutch academic biotechnology patents to the globally operating biopharmaceutical sector is significant (Restaino and Tackeuchi, 2006). However, the 47 % of co-applications of academic biotechnology patent applications filed by Dutch companies in this research turns out to be considerably higher when compared to data from earlier research (Giuri et al., 2007).

The biotechnology ecosystem in the Netherlands is small and concentrated in three clusters. In this particularly competitive sector industry, funded academic patented inventions are more likely to boost innovations (Wright, Lei and Merill, 2014). The policy instrument BioPartner enabled some 90 Dutch spin-off companies to appropriate 337 biotechnology patent applications based upon scientific research²³. By the year 2006, some 120 companies and technology institutes in three regional clusters (Leiden Bioscience Park, Utrecht and Amsterdam Science Park) were operational in the Dutch biotechnology sector. In 2014, some 590 dedicated biotechnology companies and institutes were operational in six clusters in the Netherlands (Leiden Bioscience Park, Utrecht Science Park, Amsterdam Science Park, Health Valley, Rotterdam Science Tower and Groningen Business Generator) and provided jobs for some 34, 000 full time equivalent employees (van der Giessen et al. 2014). During interviews with university managers and intellectual property managers in the industry, we found evidence that deans of university faculties and life scientists have become more aware of the importance of research commercialisation and patents (KNAW, 2014). More recently, research commercialisation and entrepreneurship have also become more important and appealing to academic scientists as a means to enhance their careers (Van Dongen et al., 2017 b).

The identification of academic patent applications and the quantification of their applicants can pose several problems. When scientific research is financed fully or partly by private companies or research funding organisations, it remains possible for other parties than universities to negotiate the filing of patent applications and their appropriation (Geuna and Rossi, 2011). Patent applications based upon academic inventions by scientists at universities may be filed by third parties and will then represent a blind spot. Given the time period of our research e.g. the KEINS database, with 1.5 million patent applications filed at the between 1978 and 2003 and administrated by the European Patents Inventor database at the Bocconi university in Italy (Lissoni et al., 2008), can provide only partially for a possibility to match these EP applications with Dutch academic biotechnology patent applications and inventors. However, we did not have access to one national database with up-to-date and accurate information about tenured academic staff. And, in line with their internal policy, some universities (e.g. Delft University of Technology), technology institutes (e.g. TNO), SMEs or spin-offs may decide to apply for national e.g. NL patent applications only, without continuations into EP patent applications.

²³ Innotact (2005). <u>http://www.BioPartner.nl</u>

In the biotechnology sector, scientific research has made significant contributions to a number of patented innovations (Sampat and Pincus, 2015; Dohlberg et al, 2017). The process to manufacture rDNA and the rDNA product itself, have been patented by Cohen and Bover in November 1974. While these 'star scientists' and academic inventors were initially hesitant to file patent applications, discussions with the US National Institutes of Health, which funded their academic research, led to the decision to support the filings of the patent applications by involved academic inventors of the university, and subsequently license agreements were signed. The company Genentech became the first company to commercialise this novel patented technology in 1976, and the first in a wave of biotechnology companies (Zucker et al., 1998). Though this case was paradoxical, the TTOs at universities in the USA gained experience with patenting and licensing of technologies based upon academic research since the 1980s (Henderson et al, 1996). Nowadays, 18 Codes of Practices for TTOs are available as recommendations for policy makers and research funding agencies in order to facilitate optimal research commercialisation in Europe (Arundel, 2013). But back in 2000, only little information was available to design university patent policies by policy makers at the national and regional levels or at the level of the individual universities (Bekkers et al., 2006). The regular exchange of experiences in matters of intellectual property rights, business development, spin-off creation and licensing, between personnel of Dutch TTOs and established university TTOs in other European countries started in 2005. Discussions within expert committees with TTO personnel (e.g. ASTP, PROTON) also contributed to a professionalisation of TTO governance and structure.

Future research into the effects of policies on the actual use and exploitation of academic patents in various economic sectors may include a wide variety of areas. The payment of annual patent renewal fees (e.g. Dechezleprêtre et al., 2017), licensing (OECD, 2013) and patent citations by third parties (e.g. Van Dongen et al., 2017a ; Hall et al., 2007) can be used as important indicators to determine their use, exploitation and value. Here, the polymerase chain reaction (PCR) technology presents an interesting but counterpointing example of the rDNA technology developed by Cohen and Boyer. The PCR technology comprises a research tool which enables specific and rapid amplification of targeted DNA and RNA sequences. Its use had a profound impact on basic research because the technology did not only made work in laboratories more efficient in time and direct costs, but it also enabled some experimental approaches that had been impossible before (Adams, 2014). In less than a decade, the PCR technology has become a standardised technology in most laboratories that run molecular biology experiments. Inventor Kary Mulis was awarded a Noble prize only eight years after a first paper on PCR has been published and the priority patent applications had been filed.

Considering the impact of the BioPartner programme, we conclude that the patenting part of this policy instrument has contributed to the sector as a whole but only on a limited scale with regard to the development of university spin-offs. Our data suggest that the 'business culture using biotechnology patents' at universities in the Netherlands has improved since the start of the programme.

AppendixInternational and Cooperative Patent Classes used for the
classification of biotechnology patent applications24

White (= industrial) biotechnology;

C02F3/34 biological treatment of water, waste water, sewage or sludge, C12M, C12N, C12P and C12Q (resp. apparatus for enzymology or microbiology, compositions of micro- organisms or enzymes, fermentation or enzyme- using processes, measuring processes involving enzymes or micro-organisms)

Red (= medical) biotechnology;

A61K38, A61K39 and A61K48 (resp. medical preparations containing peptides, antigens or antibodies, or genetic material to be inserted into cells of the living body), C07G11, C07G13 and C07G15 (resp. antibiotics, vitamins, hormones), C07K4 and C07K14, C07K16, C07K17 and C07K19 (resp. peptides having less and having more than 20 amino acids, immune globines, carrierbound or immobilised peptides, hybrid peptides), G01N33/53, -/68, -/74, - /76, -/78, - /88 and -/92 (analysing materials involving resp. immunoassays, proteins, hormones, human chorionic gonadotropin, prostaglandins and lipids)

Green (= agro food) biotechnology;

A01H1 and A01H4 (resp. processes for modifying genotypes and plant reproduction by tissue culture techniques)

²⁴ Patent classes used in PATSTAT and Espacenet, both on-line databases developed by the European Patent Organisation, <u>http://www.epo.org/searching_have been accessed in 2015</u> and 2016

Chapter **4**

Research commercialisation in Europe: a matter of governance of Technology Transfer Offices?²⁵

Abstract

Although many universities in Europe installed technology transfer offices (TTOs) in the last decades, quantitative data about their organisation, governance and performance are scarce and difficult to compare. This chapter describes: a) the relationships between four governance models of technology transfer processes (classical, autonomous, discipline- integrated and discipline- specialised) that are common at European universities, b) the engagement of scientists with research commercialisation at university TTOs, which apply these models, and c) the output of the TTOs (in terms of academic patents and spin-offs).

Using a unique European data set, scientists' engagement with industry collaboration, contract research, consultancy, filing of patents and creation of spin-offs, in relationship with the TTO governance model and their contacts with a TTO have been analysed. Key findings suggest that a classical governance model- that provides services for scientists at a centrally located office, which is fully integrated into the administration of one university- can be associated with a significant higher level of scientists' engagement with research commercialisation (e.g. patenting and spin-off creation). A Dutch case study with comparative technology transfer analyses of some 3, 400 academic patent applications, filed between 1994 and 2014, shows that the distribution in the appropriation of academic patents by multinationals or regionally operating SMEs changed significantly after the implementation of technology transfer governance models

²⁵ This chapter is identical to:

Van Dongen, P. Research commercialisation in Europe: a matter of governance of university Technology Transfer Offices? Under review at *Technovation*.

in 2004. This suggest that a discipline-integrated TTO governance model contributes to a higher level of appropriation of academic patents by SMEs in the region of the university.

This research leads to two conclusions: 1) the choice to implement a specific technology transfer governance model can have a significant impact on the level of research commercialisation like patenting and spin-off creation; 2) in the longer run, different governance models of TTOs can contribute to significantly different appropriation of academic patents by third parties.

4.1. Introduction

With the institutionalisation and dynamics of commercialisation of their scientific research results, many universities have become power houses of innovation on global level (Etzkowitz, 2008, Etzkowitz and Levesdorff, 2000). Research commercialisation has become an increasingly important topic in innovation policies in many countries (OECD, 2014) and many universities organize the commercialisation of their research via Technology Transfer Offices (TTOs). In Europe, the importance of the licensing performance of university TTOs has been described (Conti and Gaulé, 2011) as well as their positioning in networks with the industry (Debackere and Veugelers, 2005). Earlier research has unearthed relationships between changes in IPR regulations and universities patenting (Audretsch and Göpteke- Hultén, 2015; Geuna and Rossi, 2011). The mission of a university (Goldfarb and Henrekson, 2003), the presence of an engineering faculty (Van Looy et al., 2011) and the physical location of the TTO (Della Malva et al., 2009) are positively associated with the number of academic patents. However, to date only a limited number of studies present empirical evidence about the relationships between the organisation and governance of university technology transfer processes (Geuna and Muscio, 2009) and their output in terms of collaboration with industrial partners, creation of spin-off companies and the filing of patents (Schoen et al., 2014). Specifically, the relationships between national innovation policies, the governance of university TTOs and their effects on the transfer of academic patents to third parties have not been studied.

In contrast with research in the USA (Mowery et al., 2001; Jaffe et al., 1993; Acs et al., 1992; Jaffe, 1989), it has proven an almost impossible to find quantitative data showing how and whether innovation policies or national patent acts contribute to higher levels of appropriation of academic patents by companies in Europe. These data are important for national, regional and university policymakers when they design and implement new policies or programs. This research intends to bridge this gap and will examine the relationships between the governance of university TTOs and their performance and output. The chapter can contribute to literature by testing three hypotheses about the impact of the governance of university TTOs on research commercialisation. Therefore following research questions will be addressed:

- can differences in university technology transfer (TT) governance models be associated with different levels of TTO output?
- can differences in university TT governance models be associated with differences in distribution patterns of transferred academic patents, and
- which TT governance models can universities implement to stimulate the transfer of academic patents for regional economic growth and innovation?

After formulating a theoretical framework and hypotheses in **section 4.2** and describing the methodology in **section 4.3**, this chapter presents empirical evidence from the analyses of quantitative data about research commercialisation by scientists working at 148 universities in Europe. **Section 4.4** presents data on research commercialisation in association with three TT governance models that are commonly implemented at university TTOs in Europe. **Section 4.5**

presents a case study examining the impact from a national innovation policy in the Netherlands on the implementation of university TTOs and research commercialisation by scientists. Evidence-based data that TT governance models, as initiated by the implementation of an innovation policy, can indeed be positively associated with levels of research commercialisation by scientists, will be described here. As certain TT governance models may even have an influence on the distribution of transfer of academic patents to companies the findings of this research may have implications for policy makers.

4.2. Theory and hypotheses

In many member states in the EU the formal tasks of universities, i.e. education and research, have been extended with a 'third mission' of research commercialisation (RC). This process started in the 1980-ties in the United Kingdom and universities in other countries followed (Geuna and Muscio, 2009). The RC output can be defined and quantified in terms of contract research, collaboration with industrial partners, consultancy, creation of spin-offs and the filing of patents (OECD, 2014). Contract research and collaboration between universities and companies already existed for many decades, but the institutionalisation of research commercialisation via staff of university TTOs is of more recent date (Freitas et al., 2013). **Table 4.1** describes four TT governance models that have been implemented at universities in the EU (Schoen et al., 2014) and these descriptions will be used in this research.

Table 4.1.Names and description of university technology transfer (TT) governance
models and TTO locations

Name	Description of TT governance	Location of TTO
Classical, centralised (CC TTO)	Classical governance model, TTO staff only serves the researchers of one university and the office and its' personnel are integrated into the administrative structure of the university	Central on university campus
Autonomous, decentralised (Au TTO)	Autonomous governance model is similar to the classical model, but with a higher degree of autonomy from the university's central administration (e.g. budget allocation, human resources management)	Decentral at a faculty, research institute or medical centre
Disipline-integrated (DII TTO)	Disipline- <i>integrated</i> governance model, here TTO assist with TT activities of one or several universities and is organized outside a university's administrative structure	External, outside of the university campus
Discipline-specialised (DIS TTO)	Discipline- <i>specialised</i> governnace model, TTO staff assists TT activities of one scientific discipline (e.g. engineering or life sciences) of several universities and is organized outside a university's administrative structure	External

The TTO productivity performance may depend on organisational and institutional factors, e.g. TTO size, experience or regulations about IP ownership (Siegel et al., 2003) and their location (Friedman and Silberman, 2003). At the same time, it is assumed that the TTO productivity performance or RC output can be determined by the overall engagement of scientists with the commercialisation of their research (Perkmann et al., 2013).

Control factors that can be associated with the engagement of scientists with RC, are their age (Frosch et al., 2015), scientific discipline (Van Looy et al., 2011) and university position (Shane, 2004). In line with these theories, RC can then be estimated as:

(4.1) RC_{TTO} determined by $\sum RC_i = f(G_i, L_i, X_i)$

where RC_{TTO} can be measured in terms of scientists that contact their university TTO for funding, contract research, IPR and spin-off development. RC_i represent the individual engagement of individual scientist number i (i= 1, the last scientist number n) with research commercialisation. As can be seen in equation 4.1, the RC of scientists is determined by independent model variables G (governance model at a university TTO), L (location of a university TTO) and X (a vector consisting of the control variables). Following equation 4.1 and the definitions of TT governance models- described in **table 4.1**- the first hypothesis can be formulated as *HI*: the RC output of a university TTO is significantly determined by scientists' contacts with TTO. This hypothesis can be accepted on the condition that we will identify positive associations between the TTO RC output and its governance model and location.

Conform theories about the relationships between the commercialisation of patents and the organisation of TTOs (Siegel et al., 2007; Siegel et al., 2003), the use of incentives for scientists (Panagoupolis and Carayannis, 2013) and the location of a TTO (Friedman and Silberman, 2003), it can be estimated that:

(4.2) \sum (Academic patents) is determined by: $\sum P_i = f(G_i, L_i, X_i)$

where P is the number of patented inventions by individual scientist i (i= 1....n). Again, the number of patented inventions can be determined by independent model variables G (governance model at a university TTO), L (location of a university TTO) and X (vector of other control variables). Assuming that, in general, universities follow an IP policy to assign academic patents to companies the second hypothesis can be formulated as H2: The number of academic patents is determined by patenting scientists. We can accept this hypothesis if significant positive associations between academic patents and university TT governance models will be identified.

According to literature about knowledge spillovers from universities to companies it is known that these proximity effect occurs locally (Acs et al., 1992; Jaffe, 1989). The research methodology in these studies is based on a (modified) knowledge production function (Griliches, 1979) showing that the effects from academic research on the number of corporate patented inventions. The states in the USA and broad technological areas were used as units of

observation, and the number of corporate patents was found to be positively associated with research at a local university (Jaffe, 1989). A further analysis between co- localization, patents and patent citations showed that the advantages of the proximity effect decrease over time (Jaffe et al., 1993). But the impact of academic research on regional innovation is not only affected by geographical proximity, but also by university- industry collaboration (Ponds et al., 2010; Boschma, 2005). A study about the propensity to start a company at locations in the proximity of a university showed that this phenomenon was highest in those industries where tacit knowledge plays an important role (Audretsch and Feldman, 1996). TT governance models of university TTOs have not been taken into account as independent variable in studies about knowledge spillovers or university-industry collaboration. Focusing on academic patents to companies in the region, proximate to a university, can be associated with a specific TT governance model at that university. This hypothesis will be accepted if differences in the assignments and transfer of academic patents can be positively associated with differences in university TT governance models.

4.3. Methodology and data

An international survey in Europe was conducted to collect RC data from individual scientists directly. Data for the years between 2010 and 2015 have been collected to measure if scientists become more engaged with RC in recent years. To avoid potential problems e.g. conflicts of interest, data of interdependent variables and TTO staff, deans or university directors were excluded from participation. The unit of analysis in this research is a scientist who has been engaged with research commercialisation with or without the services from TTO staff. The survey questionnaire contained four sections to collect following data;

- a) Scientist's engagement with RC in general and with patents and spin-offs in particular;
- b) TT governance model of, contact with and quality of the university TTO;
- c) Regulations on IP use, patent ownership at their university and the importance of patents for commercialisation of their research results and career, and
- d) Individual data of the scientist (e.g. age, university position, scientific discipline).

The sample with the size of the potential target audience for this research can be determined, following Giuri et al. (2007) thus assuming that the majority of IP related RC activities is carried out by PhD students and (associated/assistant) professors. With a total population in the EU of approximately 508 million persons (in 2010) and with a 0.2% of them having received an education at PhD level at universities (Eurostat²⁶), the target audience in this research consist of approximately 1 million scientists. Using a confidence interval of 95% and an accuracy rate of 2% a recommended sample size (n) of 2, 396 scientists can then be regarded as minimum threshold for a representative survey (Brian and Jenkins, 2013). From the *Web of Science* database at the Centre for Science and Technology Studies (CWTS) of the Leiden

²⁶ <u>http://ec.europa.eu/eurostat/data</u>, accessed for census about scientists at European universities in 2016, 2017

University in The Netherlands, some 60, 000 email addresses of European scientists working in all disciplines were randomly selected. Next, the questionnaire was digitally submitted and the reception of the email was confirmed for almost 50% of the email addresses of some 150 universities in 30 countries in Europe. Participation in the survey was voluntary, anonymous and respondents were not financially reimbursed. During the survey the target audience received five follow-up messages between November 2015 and March 2016, and participants received a report with summarized results by June 2016. At the close of the survey responses (mostly fully filled-out questionnaires) from 2, 665 scientists working at 148 universities in Europe have been received. This low response rate of 8.9% was expected and is acceptable since it exceeds the required threshold sample size of 2, 396 scientists.

In a country case study the impact of the Technopartner program in the Netherlands has been examined as an instrument to measure the effects of the implementation of TTOs. Effective from 2004, this program enabled the introduction of various TT governance models at universities and the impact of this innovation policy instrument on research commercialisation e.g. academic patents can be measured. In 2015 approximately 42, 000 FTE were employed by the Dutch universities as scientists in all disciplines (http://www.vsnu.nl/en). With a confidence interval of 90% and an accuracy rate of 5%, a sample size (n) of 268 scientists can then be regarded as representative for the Dutch survey. As in chapter 2, academic patents are defined as the assembly of both university-invented and university-owned patents, with the criterion that tenured university staff is mentioned as inventor in the patent application (Lissoni, 2012). From the open source KNAW databases (https://dans.knaw.nl/) and with the assistance of the departments of Human Resources of the universities the names of some 65, 000 tenured scientists were collected. The same methodology described in chapter 2 and developed by the Fraunhofer Institute (Dornbusch et al., 2013), was applied to identify and quantify academic patents from Dutch origin. Two algorithms were applied to match the names of university employed scientists with the names of inventors in patent applications with an origin in the Netherlands (Van Dongen, Winnink and Tijssen, 2014).

After identification, quantification and validation all academic patents were organised by university of origin of the invention and categorised by its university TTO governance model in two datasets covering the time period between 1994 and 2014. Here universities, public research organisations (PROs), domestic companies including university spin- offs and foreign organisations (with headquarters outside The Netherlands) have been taken into consideration as patent applicants. Because the filing of academic patents from 2004 onwards can be associated with the start of the Technopartner program, including the implementation of TTOs with different TT governance models, a distinction was made between academic patents filed in the time frame before and after 2004. Names and patent data from alumni start-ups and university spin-offs were collected from the evaluation reports of the Technopartner program²⁷ and also matched with identified academic patents.

²⁷ <u>Technopolis-evaluation-technopartner</u>

4.4. Results ²⁸

The survey yielded data of 2, 665 scientists working at some 148 universities in 30 countries in Europe. After validation the survey contains a dataset from 2, 645 scientists at the faculties of earth, engineering, mathematics and ICT, medical, life sciences and health and social, economics and humanities. The majority of respondents is older than 35 years, male and has a position as associate- or assistant professor in the medical, life sciences, health and engineering sciences. In general, the IP awareness amongst all participants was surprisingly high at some 80%, thus including scientists at the faculties of economics and sociology. **Table 4.2** shows the

Variables	Number of Scientists	Scientists (%)	RC engaged scientists (%)	Patenting scientists (%)	Spin- off involved scientists (%)
	2,665	100.0	31.7	16.4	6.6
Data					
1.Age < 35 years 35 -50 years >50 years	573 1, 101 991	21.5 41.3 37.2	25.1 34.2 33.2	8.5 19.3 20.3	No data
2.Scientific disciplines Earth Engineering Mathematics and computer sciences Medical or Life sciences and health Natural Social, economic and humanities Not indicated	94 504 218 810 453 134 452	3.5 1.9 8.2 30.4 17.0 5.0 17.0	28.7 45.4 31.7 32.5 31.6 20.9	5.3 26.8 7.2 18.4 24.1 0	5.3 12.5 9.2 5.5 12.2 2.2
3. University position PhD student Post doc Associate or assistant professor Professor Other No data	156 496 765 582 202 464	5.9 18.6 28.7 21.8 7.6 17.4	13.5 26.0 34.9 46.6 33.7	4.5 11.5 18.3 29.4 19.8	3.2 5.6 6.7 12.2
4. Scientists that did or did not contact their university TTO With contact No contact Not applicable No data	524 421 152 1, 568	19.7 15.8 5.8 57.3	50.9 10.8	69.1 7.8	69.1 18.3
5.TT governance models confirmed by scientists Classical, centralised TTO Autonomous, decentralised TTO Discipline- integrated, regionalised TTO Discipline- specialised Other No idea Not applicable No data	621 124 56 No data 22 134 73 1, 635	23.3 4.7 2.1 No data 0.8 5.1 2.8 62.0	See table 4.3	See table 4.3	See table 4.3

Table 4.2.Summarized statistics (*)

(*) in case of shortage of data the total percentages may not match exactly 100 %

summarised statistics on scientists' engagement with research commercialisation, patenting and spin- off creation (resp. 32, 16 and 7%). These overall results show that elderly scientists at

²⁸ The original survey dataset has been deposited at the repository of the Royal Netherlands Academy of Arts and Sciences. These data are publically accessible at <u>https://doi.org/10.17026/dans-xgg-r2nu</u>

senior positions (associate/assistant) professors in engineering, natural or life sciences are most engaged with research commercialisation, patenting and spin-offs. Only 51% of the scientists who are RC engaged, contacted their university TTO, but these percentages of scientists contacting their university TTOs are much higher for those engaged with patenting and spin-off creation. It is also evident that the classical TT governance model with a centrally located TTO is most frequently contacted by scientists. Most interesting is the finding that scientists who are most engaged with RC activities (e.g. patenting or spin-off creation), contacted classical governed TTOs at a central location. Another interesting observation is that 8–18% of responding scientists is involved with patenting and spin-offs without any assistance from the TTO staff of their university. One can observe that the discipline-specialised TT governance model was not distinguished as such by scientists, while 22 scientists responded that at their university the TT governance model need to be described in other ways.

Since the discipline-specialised TT governance model has not been recognized as such by scientists this TT governance model will be not be included in following analyses and discussion. Using the total number of 524 scientists (**table 4.2**, item 4) who contacted their university TTO with a specific TT governance model, the results from the statistical rank correlation analysis between pairs of variables are shown in **table 4.3**. Considering the number of respondents, a confidence interval of 95% and an accuracy rate of 5% a sample size of 334 scientists exceeds the threshold sample for statistical analyses about the impact of university TTO contact. The results in **table 4.3**. show that both the percentages of scientists that contacted their TTO and RC engaged scientists differ significantly per TT governance model.

Table 4.3.	Relationships between technology transfer (TT) governance models and
	scientists engaged with research commercialisation (RC) at universities in
	Europe

TT governance model/ TTO location at university	Scientists that contacted a TTO with this TT governance model (%)		RC engaged scientists (%)		Patenting scientists (%)		Spin-off involved scientists (%)	
Classical TT model / centralised TTO	75.4	RCC 0.88	80.0	RCC 0.46	80.4	RCC 0.53	84.9	RCC 0,4
Autonomous TT model/ decentralised TTO	14.1	(***)	14.1	(***)	12.5	(***)	6.7	(***)
Discipline-integrated/ regionalised TTO	5.2		4.1		5.4		5.0	
Other	5.3		1.9		1.7		3.4	

N = 524 RCC= rank correlation coefficient, bivariate Spearman rank correlation analyses (***) highly significant at 0.01 level (two-tailed)

The correlation coefficient between TT governance models and the percentage of scientists that contact a certain TT governed TTO (i.c. classical, autonomous, discipline –integrated) is significant, positive and high. The correlation coefficient between TT governance models and scientists engaged with research commercialisation is positive and medium high. This analysis shows that the production performance of a classical TT governance model with a centrally located TTO can be associated with: 1) the highest percentages of contact between scientists and the university TTO, and 2) with the highest percentages of RC engaged scientists' (including patenting and spin-offcreation).

Looking at **table 4.3.** with the results from the statistical analysis, *H1*, stating that RC output of a university TTO is significantly determined by scientists' contacts with TTO, hence positively associated with the TTO location and TT governance model, can be accepted.

National innovation policies may not only affect research funding, IP rules and regulations, hence number of academic patents (see chapter 2) but also the implementation of TTOs and their TT governance model. Although the data in **table 4.3.** would allow the acceptance of H2, stating that the number of academic patents determined by patenting scientists can be positively associated with university TT governance models, the acceptance of this hypothesis requires further study in a national context.

4.5. A case study on the impact of university TTO governance models in the Netherlands

The relationships between, and the effects of an innovation policy on university TTO governance models, research commercialisation and the transfer of academic patents in The Netherlands will be described. Since 1995, the Netherlands' Patent Act provides universities the same ownership entitlement as the Bayh-Dole Act does in the USA. Some universities in The Netherlands provided RC services for scientists, but their limited human and financial resources, the outreach of TTO staff and their output (i.e. invention disclosures, patents, spinoffs) are limited (VSNU²⁹). The Netherlands' innovation system, the high quality of scientific research and the high rate of (company) patenting were considered positive features. But the role and position of universities as serious actors in the innovation system was relatively weak and their budgets did not include substantial resources for research commercialisation, TT or spin-off creation (OECD, 2005). On the contrary, the low level of private R&D, the less than optimal interaction between industry and academia, insufficient innovative entrepreneurial activity at universities and the limited capacity for research commercialisation were considered negative features (OECD, 2005).

In 2003 the Netherlands' government initiated the Technopartner program with a special Subsidy for Knowledge Exploitation (SKE) as policy instrument, enabling universities to install

²⁹ http://www.vsnu.nl/facts-and-figures.html accessed in 2015 and 2017

or develop their TTOs applying different governance models for TT³⁰. This program also provided schemes to universities to professionalize their patent policy and reimbursed 50-70% of the costs of patent applications after licensing an academic patent to a start-up company or transferring a patent to a company. The general objectives of the program were to increase the number of start-ups and spin-offs improving their quality by mobilizing risk capital through a seed fund facility. The program was operational between 2004 and 2010 and is comparable with the SBIC³¹ program in the United States. The Technopartner program will be used to measure the effects of the implementation of a national innovation policy on the governance of TTOs and research commercialisation.

For the interpretation of the analysis of the data from this research, some typical characteristics of the development of TT governance models at universities in The Netherlands have to be taken into consideration (KNAW, 2014). At a classical-centralised TT governance model (CC TT) the board is responsible for most decisions (e.g. funds for filing of patent applications, rules about IPR ownership, transfer of IPR to spin-offs, incentives for academic inventors). In an autonomous-decentralised TT governance model (AU TT) this mandate is in the hands of a faculty dean, faculty contract managers or with the TTO manager and the TTO is usually located at a faculty or at a medical centre. In a discipline-integrated, regionalised TT governance model (DI TT) the university board aligns its TT strategy with companies and a regional economic development board. In the Netherlands the discipline-specialised TT governance model (DS TT) was not operational. Table 4.4 shows the summarized data of the TT governance models and location of the TTOs for eight out of twelve universities in the Netherlands

University	Scientific disciplines	TT governance model (a)	Location of TTO	TTO name
Wageningen University	Plant breeding, earth and life science	Discipline- integrated	IPR helpdesk on campus	None
University of Twente	Engineering and business	Discipline- integrated regionalised	Outside campus	Kennispark Twente kennispark
Delft University of Technology	Engineering and business	Autonomous, decentralised	Within one faculty	Valorisation centre Valorisation centre
Eindhoven University of Technology	Engineering and economics	Classical, centralised	On campus	TU/e innovation lab innovation-lab
Radboud University Nijmegen	Medical, life sciences and health, economics	Autonomous, decentralised	Close to medical centre and faculty of science	Directorate Valorisation Valorisatie
Free (VU) University Amsterdam	Earth, medical, life sciences and health, economics	Developed from classical, centralised to discipline-integrated regionalised	On campus	TTO VU & VUMC vumc.nl/onderzoek
Leiden University	Medical, life sciences and health, social	Classical, centralised	Close to medical centre and faculty of science	LURIS luris
Utrecht University	Medical, earth, life sciences and health, economics	Classical, centralised	On campus	Holding utrechtholdings

Table 4.4. Technology transfer (TT) governance models and the location of university TTOs for eight universities in the Netherlands

^(a) TT governance models are described in table 4.1 and their RC results are mentioned in university annual reports

pages 84 and 85

³⁰ <u>https://technopartnerin the Netherlands-</u> ³¹ <u>https://www.sba.gov/sbic</u>

The Technopartner program enabled twelve consortia consisting of universities, companies and regional development agencies to file 760 patents³². During the program some 700 start-ups have been created, which by the year 2010 provided jobs for approximately 1, 800 FTE. During the Technopartner program, the universities were the lead partners in the consortia providing RC services like business development and IPR. At the same time, each university could develop an appropriate TT governance model and IP strategy aligned with its mission and stakeholders. We applied the same methodology to identify academic patents (see **chapters 2 and 3**) matching the names of tenured scientists at these eight universities and medical centers with patents that have been filed between 1994 and 2014 to study the impact of the Technopartner program. Acknowledging that it may take 10 years to observe the impact and effect of policy, we studied the number of patent application filed 10 years before and 10 years after the implementation of the program (2004) and quantified some 3, 400 academic patent applications. These patents can be aligned with the three TT governance models of the TTOs in this study.

Next, we used the data from 328 Dutch scientists which we retrieved from the European survey (section 4.4.). **Tables 4.5 and 4.6** show the general data of the RC survey amongst scientists at eight universities in The Netherlands, respectively the results of the statistical analysis of these data. Compared with data from scientists at universities in other countries in Europe, the autonomous governed university TT model with a decentral located TTO office is more common at Dutch universities and more frequently contacted by scientists. One can observe that in the Netherlands more RC engaged scientists have been assisted by the TTO staff, as compared with their peer scientists in other countries in Europe. Especially, the number of scientists that contacted their university TTO when involved in the creation of a spin-off is

Variables	Number of scientists	Scientists (%)	RC engaged scientists (%)	Patenting scientists (%)	Spin-off involved scientists (%)
	328	100	3.4	18.3	4.9
Data					
1. Scientists that did or did not contact their university TTO With contact No contact Not applicable No data	79 18 20 211	24.1 3.0 6,1 64.3	51.6 8.7	75.0 6.7	93.8
2. Confirmed TT governance models by scientists Classical, centralised Autonomous, decentralised Discipline-integrated Other No idea Not applicable No data	55 40 1 3 27 5 197	16.8 12.2 0.3 0.9 8.2 1.5 60.1			

Table 4 5	Summarised	statistics for	eight unive	ersities in	the Netherlands	(*)
1 abic 4.5	Summariseu	statistics for	cignt unive	ci sitics in	the rether lanus	いり

(*) The totals of the percentages may not match 100%

32 http://evaluation-technopartner-program

much higher. Because of the smaller sample size, we reduce the confidence interval till 90% and applied an accuracy rate of 10% so that a minimum sample size of 68 persons suffices for further statistical analyses. The results in **table 4.6** show statistically that TT governance models can be positively associated with significant differences in numbers of scientists that contact their TTO and RC-engaged scientists. The correlation coefficient between TT governance models and the percentages of scientists that contact TTOs which are governed by such model is significant, positive and high. The correlation coefficient between TT governance models and the percentage of RC-engaged scientists is positive and medium high. Based upon these statistical analyses, both *H1 and H2*, stating that the RC output of a university TTO is significantly determined by scientists' contacts with TTO (hypothesis 1), respectively that the number of academic patents determined by patenting scientists can be positively associated with university TT governance models (hypothesis 2), can both be accepted for universities in The Netherlands.

Table 4.6.Relationships between TT governance model and scientists engaged with
research commercialisation (RC) in the Netherlands

University TT governance model	Scientists that contacted a TTO with this type of TT governance model (%)		RC engaged scientists (%)		Patenting scientists (%)		Spin –off involved scientists (%)	
Classical, centralised TTO	55.2		62.9		65.1		53.3	
Autonomous, decentralised TTO	42.1	RCC 0.86	35.5	RCC 0.49	30.2	RCC 0.53	40.0	RCC 0.41
Discipline-integrated, regionalised TTO	1.3	(***)	0	(***)	2.3	(***)	2.7	(***)
Other	1.3		1.6		2.3		0	

RCC= rank correlation coefficient, bivariate Spearman rank correlation analyses (**) significant at 0.01 level (two-tailed)

The effects of the implementation an innovation policy on the development of different TT governance models and the transfer of academic patents have been examined in this case study. Although, some universities already institutionalised facilities for research commercialisation by mid-1990s the Technopartner program was taken as a starting point for this part of the research. Thus the year 2004 has been used as the division line for the implementation of a TT governance model and choice for a location of a university TTO. Academic patents have been categorized per university where the scientific research took place on the basis which a patent has been filed and the scientist was tenured and mentioned as inventor at the date of filing of the patent application. **Figure 4.1** shows the differences in developments in the appropriation of academic patents by six categories of applicants (university self, public research organisations (PROs), multinational corporations (MNCs), small and medium sized entreprises (SMEs), university spin-offs (also including the alumni start-ups) and organisations with headquarters outside of the Netherlands (Foreign org.), distinguished by TT governance model

over time. With the institutionalisation of university TTOs and the implementation of TT governance models in 2004, one observes that, contrary to the objectives of Technopartner, less academic patents have been appropriated by spin-offs.

Figure 4.1. Six categories of academic patents before 2002 and after the implementation of different TT governance models (%)

4.1.a. Classical TT governance model at a centralised TTO (CC TTO, e.g. Leiden University, Utrecht University and Eindhoven University of Technology)



4.1.b. Autonomous governance TT model at a decentralised TTO (Au TTO, e.g Delft University of Technology, Radboud University Nijmegen)



N=391 (between 1994 and 2003 in black colour) N=551 (from 2004 till 2014 in red colour)

4.1.c. Discipline- integrated TT governance model at a regionalised TTO (DII TTO, e.g. Wageningen University, University Twente and Free University (VU) Amsterdam)





N= 332 (from 2004 till 2014 in red colour)

Figure 4.1.a shows that three universities which implemented a *classical* TT governance model since 2004 with a centrally located TTO, i.e. Universities of Utrecht and Leiden and the Eindhoven University of Technology, filed (35% of 768)/(10% of 919) = 2.9 times as many patent applications than before the year 2004. On the other hand, only half as many patents (=22% of 768/38% of 919), originating from research at these universities, have been appropriated by Dutch multinational companies (MNCs). Figure 4.1.b shows that universities that implemented an autonomous TT governance model with a decentralised TTO (e.g. Radboud University Nijmegen and Delft University of Technology) filed five times more patents since 2004. Here, one can observe that Dutch multinationals appropriated (23 % of 551/ 33% of 391)= two thirds less academic patents. Figure 4.1.c that also universities which implemented a discipline- integrated TT governance models, with a regionalised focus (i.c. University Twente, Free (VU) University Amsterdam and Wageningen University and Research Centre) filed (34% of 332/6% of 435) = 4,3 times as many patents compared with the situation prior to 2004. So, independent of the implementation of any TT governance model after 2004 all Dutch university filed more patent applications which can be attributed towards the policy of Technopartner. But a key finding in this case study is that only those universities that implemented TTOs with a discipline-integrated TT governance model performed in such a way that Dutch SMEs, which are located in the region of a university appropriated twice as many academic patents than before the implementation of a university TTO.

The number of scientists, who engaged with patenting, also increased with the introduction of a this new innovation policy. Prior to the year 2004, a different policy instrument of the Dutch government (BioPartner program) enabled scientists in the life sciences to start spin-offs and file patents. **Table 4.7** summarizes all academic patent data presented in **figure 4.1**. about the appropriation of academic patents which occurred after the implementation of a new innovation policy in The Netherlands in 2004, when the Technopartner program was implemented. The data in this table show striking differences in appropriation in the time period before (1993-2003) and after the start of Technopartner (2004-2014). These differences can be associated with the implemented university TT governance models and the IP policy of a university. Comparing these patent filing data before and after the implementation of TT governance models, one can observe that: 1) universities filed a higher percentage of patent applications since 2004; 2) Dutch MNCs and foreign organisations appropriated a lower percentage of academic patents; and 3) Dutch SMEs appropriated a higher percentage of academic patents, originating from research at those universities that implemented a discipline- integrated TT governance model.

Looking at patent distribution data in **figure 4.1** and **table 4.7**, hypothesis *H3*, stating that the transfer of academic patents to companies in the region, proximate to a university can be associated with a TT governance model implemented at that university, can in this case study be accepted for universities in the Netherlands.

Table 4.7.Differences (%) in academic patents appropriation by their applicants
before (1993–2003) and after the implementation of university technology
transfer governance models (2004 -2014)

		()	
	Academic patents ^(a) categorised by model		
Patent applicant	Classical governance model	Autonomous governance model	Discipline- integrated governance model
Universities	+25	+42	+28
PROs	+ 4	-2	-8
Domestic MNCs	-16	-10	-12
Domestic SMEs	+1	-12	+11
University spin-offs	-4	-4	-6
Foreign organisations	-3	-14	-16

(a) + indicates an increase and - indicate a decrease compared to time period 1993-2003

4.6. Limitations

Although the response rate of European, including Dutch, scientists was low, the survey yielded representative data for scientists working at universities. Potential problems, e.g. dealing with a larger percentage of non- responses for some questions about RC activities in relationship with university TT governance models, could be solved by either accepting a lower confidence interval or a higher accuracy rate.

If future policy makers at national and university level want to boost the regional economic growth and apply studied TT governance models one should realise that additional variables e.g. national innovation policy, university mission, research funding, IP regimes, contract law and academic entrepreneurship culture will exert their effect and have to be taken into consideration.

The actual number of academic patents in the Dutch case study can be higher than the numbers we found, as the data sources of tenured academic staff may not be a 100% complete. Following the research methodology, all identified academic patents have been validated in cooperation with university TTO staff. Therefore, it is expected that more than 95% of all academic patents has been identified. In the Dutch case study, the dataset of academic patents is large enough to justify the acceptance of the third hypothesis for one of the studied TT governance models.

4.7. Conclusions and discussion

The research data in this chapter, suggest that:

- a. The RC output of European university TTOs can be associated with their TT governance model and the highest RC output is realised at universities with a TTO that applies a classical governance model and is centrally located at a university;
- b. The patent output of a university TTO as determined by the level of patenting by their scientists, can be associated with the TT governance model at a European university;
- c. The implementation of a discipline- integrated TTO governance model at university TTOs in The Netherlands, contributed to the appropriation of a significant higher level of academic patents by SMEs in the region, where the university is located;
- d. The implementation of studied TT governance models can be associated with lower appropriation in numbers of academic patents by domestic multinationals and SMES, and with much higher filings by universities themselves.

In line with previous qualitative research (Siegel et al., 2003) our data provide new empirical and quantitative evidence for European universities, showing that the university TTOs output, in terms of research commercialisation by (e.g. patents and spin-offs) is positively associated with its organisation and governance model for TT. Positive and high correlation coefficients were found between university governance TT models and contact with researchers, that might also be attributed to its' location (central, decentral or outside the university campus). Medium high correlation coefficients were found between patenting and spin-off creation on the one hand, and university governance models for TT on the other hand.

Our findings on the effects of patent transfer in the autonomous, decentralised governance TT model differ from results from sixteen European case studies (Schoen et al., 2014), which, contrary to our methodology, have been based upon interviews with TTO staff and TTO data from university websites. A survey at eleven European university TTOs (Debackere and Veugelers, 2005) yielded data providing evidence of increased patent transfer to spin-offs that universities with an autonomous, decentralised model for TT on the condition that a TTO can provide the right incentives for RC engaged scientists. Case studies on university–industry TT in Italy (where universities reinstalled the "professors' privilege") show the success of centralised governance models for TT with an IP strategy focusing on academic patent appropriation by firms (Rossi, 2010). At the same time, university TT towards SMEs depends to a large extent on personal contacts between scientists and entrepreneurs (Freitas et al., 2013). Case studies in Sweden (another country with universities with a "professors' privilege", and where university TTOs did not facilitate RC pathways at all, e.g. patenting) describe successful pathways for TT and development at two universities where graduates and postdocs were allowed to exploit academic inventions in start-ups (Åsterbro et al., 2012).

Our findings that for effective TT, the choice to implement specific TT governance models better also be based upon scientific disciplines at a university (engineering, computer sciences vs. medical, life sciences and biotechnology) and sectors in which, regionally companies operate is in line with the literature (Cooke, 1997; Lissoni, 2013; 2012). Our data do not clarify whether academics are best positioned to further develop an invented technology or whether that is best left to companies (Peeters et al., 2015). The exploitation of academic patents by start-ups³³ is a proven vehicle to commercialise engineering inventions and can also be successful in other sectors, like the life sciences, provided that young entrepreneurs will be in a position to team-up with experienced entrepreneurs in that sector (Van der Steen et al., 2010). On the other hand, biopharmaceutical firms are often in a better position than university spinoffs to bring biotech inventions to the marketplace, since regulators find it increasingly difficult to approve new biologicals and medical products (Konara et al., 2016).

From an institutional point of view the Netherlands' Patent Act provides universities the same ownership entitlement as the Bavh-Dole act does in the USA. However, the increase in numbers of university patents in The Netherlands has been far less spectacular than in the USA (Henderson et al., 1996; Mowery et al., 2001), which might be due to the facts that patent filing is of more recent date, lack of IP awareness or funding (KNAW, 2014; Lissoni, 2012). The alignment between national innovation policy, introduction of university governance models for TT and IP strategy has proved to be a lengthy process that started in 2004. From 2012 onwards, university boards and TTO managers were advised to align their TT governance model and the IP strategy with R&D managers of Dutch multinational firms and regional development agencies (IP paragraph in the Top Sector policy³⁴, 2013). The Dutch case study shows that the numbers of academic patents filed by universities has grown substantially after the implementation of all TTO governance models. Although a national study showed that some 66% of the academic patents have been sold or licensed to companies (KNAW, 2014), university TTO managers still receive criticism for their lack of support to scientists and entrepreneurs who want to start a company based upon academic inventions (Technopolis, 2015).

Since the regulations and practices of university TTOs in The Netherlands fully comply with six points of the Code of Practice, and reasonably well with the remaining twelve points (Arundel, 2013), the findings from the case study can be relevant for (university) policy makers in other EU countries. For policy makers who intend to extrapolate these findings or implement some of them at universities in other countries, a number of additional variables (i.e. national innovation policy, research funding, patent law, university mission, university IP regimes, contract law and academic entrepreneurship culture) will have to be taken into consideration as well. In fact, university IP regimes may significantly contribute to higher levels of academic patenting by those universities applying the policy to license these patents to (spin-off) companies themselves³⁵. The relationships between these additional variables and the engagement of scientists with RC merit future research in multiple ways (see chapter 5).

Since the RC output of university TTO governance models as the independent variable, may also be dependent from other variables that have not been examined in this research (e.g. IP awareness, obligation to contact a TTO for patents, patenting by scientists as important factor

 ³³ <u>Valorisation at 4 TU</u>, 2016
 ³⁴ <u>government.nl/encouraging-innovation</u>
 ³⁵ McDonald LURIS, Leiden University, personal communication on university IP licensing policy, 2017

for their career or contract research) further research is needed to describe and estimate these interdependencies. The research methodology and key findings of this research may serve as a starting point for scientists in their future research.
Chapter 5

The relationships between university IP regimes, scientists' motivations and their engagement with research commercialisation in Europe ³⁶

Abstract

Most policy makers regard university TT Offices (TTO) as the vehicle of university IP regimes and as the main driver enabling research commercialisation (e.g. academic patenting). In a comparative study we applied a novel typology of university IP regimes to analyse the relationships between these IP regimes and the engagement of scientists with research commercialisation. We also studied the relationships between some of the internal driving forces that can motivate individual scientists to engage in the commercialisation of their research.

In this study, we use a pan-European survey with data of approximately 2,650 scientists across some 150 universities in 30 countries, covering a the period 2010-2015. Our results shows that 32% of the scientists is engaged in various modes and pathways of research commercialisation (collaborative and/or contract research, consultancy, including patenting (16%) and/or spin-off

³⁶ This chapter was published as:

Van Dongen, P., Yegros, A., Tijssen, R. and Claassen, E. (2017). The relationships between university IP regimes, scientists' motivations and their engagement with research commercialization in Europe, *European Journal of Law and Technology*, (8), 2, <u>http://ejlt.org/article/view/567</u>

Research data were presented during an 'IPR and Economics' seminar at Bocconi University in Milan, September 2017, <u>http://eiptn.astonwordpress.co.uk/</u> and at a 'Entrepreneurship' conference at Ghent University, May 2018, <u>https://www.ugent.be/innovatie/cer/research-workshop</u>

creation (8%). At universities where a) university ownership on research results is regulated by national law, and where b) in case of research commercialisation scientists are obliged to contact a centrally located TTO, we found a significantly higher engagement (39%) compared with their engagement at other university IP regimes (which varied from 31-34%). With regards to examined individual, driving forces we found c) significantly higher levels of engagement (44-55%), d) double the amount of patenting and e) three times more involvement with the creation of spin-offs by entrepreneurship-driven scientists compared with research- or recognition-driven scientists. The creation of IP-based spin- offs was only positively associated with the drivers of scientists but not with university IP regimes.

We conclude that both driving forces that motivate scientists and university IP regimes contributed significantly to scientists' engagement with the commercialisation of their research (including patenting and spin-off creation), but the *individual* factors are by far more important than the *institutional or organisational* factors.

5.1. Introduction

5.1.1. Background

The importance of research commercialisation (RC) and the transfer of patented technologies as a contribution to innovation is beyond discussion (Brody, 2016). National innovation policies may contain intellectual property rights (IPR) laws and in the last 10 years, many countries in the EU adopted Bayh-Dole like patent legislation to regulate ownership on research results (OECD, 2013). Only universities in Italy and Sweden adopt a person-entitled-"professors' privilege". The effects of changes in regulations about IP rights (IPR) on academic patenting in Europe have been studied extensively (Lissoni, 2013, Lissoni et al., 2009, Geuna and Rossi, 2011, Smith et al., 2010).

Some EU universities have been involved with research commercialisation for more than 30 years, increasingly through their dedicated organisation units for technology transfer (TTOs). RC services of a TTO usually involve collaborative research, contract research and consulting (Perkmann et al., 2013). Some TTOs provide services for scientists to file patents and assist with the creation of spin-offs companies (OECD, 2013). So the output of TTOs can be measured in terms of start-ups or spin-offs (Muster et al., 2008; Fini et al., 2010), academic patents (Lissoni, 2012) or technology licensing (Conti and Gaule, 2011). Other researchers found positive effects of the use of incentives to involve scientists in research commercialisation (Panagopoulos and Carayannis, 2013). As TTOs are regarded as the key actor and primary driver for research commercialisation (Marion et al., 2012) the size, years after inception, expertise and experience of TTO staff have been studied as performance indicators (figure 1.3, Siegel et al., 2007, Markman et al., 2004). In this research we will study the engagement of individual European scientists with various pathways of RC and focus on patenting of their research results and creation of spin-offs based upon their IPRs.

5.1.2. University IP regimes and patent- based research commercialisation

At university and personal level, a number of institutional, organisational and individual factors can determine the engagement of scientists in the commercialisation of their research (see **figure 1.4.** in chapter 1). The relationships between the individual factors of scientists and their engagement with research commercialisation require further research (Perkmann et al., 2013). Emphasis on IP awareness amongst scientists contributed to making patenting important for scientific careers (Van Eecke et al., 2009). Various governance and organisation models for university TTOs exist (Geuna and Muscio, 2009), but the effects of the relationships between organisational factors (e.g. central location, obligatory services for university staff) of a TTO and output in terms of IPR-based research commercialisation are not evident and require further research. The European Commission drafted the EU Codes of Practice for Technology Transfer (Arundel, 2013) but the effects of university IP regimes (defined as the combined effect of national IP legislation on academic research and the institutionalised use of university TTOs to commercialise university research) to optimize research commercialisation are still unknown.

Table 5.1. describes how university IP regimes can be defined and determined by: a) national regulations on university IP ownership on research results, b) an institutionalised university TTO at central level, providing obligatory research commercialisation services for scientists, and c) the quality of TTO services. In a comparative analysis of the results of the organisational factors that may determine the scientists' engagement and hence the effects of research commercialisation, four categories of university IP regimes ('types') can be distinguished:

- *EU `full service` type*: university IP ownership, with obligatory use of the research commercialisation (RC) services provided by, a centrally located TTO;
- *EU 'optional service' type*: university IP ownership, without obligatory RC services at a university TTO;
- Italian type: 'professors' privilege, with obligatory RC services at a university TTO;
- Swedish type: professors' privilege, without obligatory RC services at a university TTO.

Table 5.1.Typology of university IP regimes for research commercialisation in
Europe (*)

	Obligatory research commercialisation services for scientists at centrally located university TTO and its quality (good/ reasonable/ not sufficient)		
University IP ownership on academic research regulated by national law	YES	NO	
YES	EU 'full service' type	EU 'optional service' type	
NO	<u>Italian type</u>	Swedish type	

(*) Adapted from Arundel (2013); Von Proff et al. (2012); Geuna and Rossi (2011); Lissoni et al. (2009) and Janssens, (2005)

5.1.3 Individual motivations of scientists to engage with patent-based research commercialisation

Research data about the driving forces that motivate scientists to commercialise their research are scarce (OECD, 2013). Apart from the USA and some EU countries, few studies present cross-national comparative analyses why scientists engage in research commercialisation (Perkmann et al., 2013). In the USA (Walsh and Huang, 2014; Shane, 2004) access to extra funding or legal obligations proved to be the most important drivers for scientists to engage in university–industry TT (Mowery and Sampat, 2005). Other studies describe scientists' drivers in a particular economic sectors (e.g. biotechnology, Patzelt and Brenner, 2008), or the importance of the scientists' drivers at the start of new technologies (Zucker et al., 1998). Most studies present country- level data only (D' Este and Perkmann, 2011; Lam, 2010; Grimpe and

Fier, 2010; Haeussler and Colyvas, 2011, Nagaoka and Walsh, 2009). This gap in knowledge about academic engagement in RC is surprising because such data can provide important input for policy advisors at university, national and EU level when designing science and innovation policies. For university managers such information is important in new strategic plans including knowledge and technology transfer. Following Lam (2010), we applied the same set of driving forces that can motivate scientists at EU universities to engage in research commercialisation: a) *Recognition-driven* (i.e. create visibility, societal impact, win 'prizes'), b) *Research-driven* (i.e. create business opportunity, economic impact, 'cash in' on eminence). In this chapter, we will describe such driving forces as scientists' drivers.

This research addresses following questions:

- How to determine if, and to what extent, European scientists are engaged with RC?
- How to identify which of the driving forces, that motivate scientists to engage in RC, can be associated with significant higher levels of RC, patenting and spin-off creation?
- What university IP regime can be associated with highest scientists' engagement with RC and subsequent levels of academic patents and creation of IP-based spin- off companies?

5.2. Methodology and information sources

Prior studies have unearthed a range of factors that can be associated with the engagement of university researchers in research commercialisation: age of a scientist (Frosch et al., 2015), scientific discipline (Perkmann et al., 2013), position at a university (Shane, 2004). We use age, gender, scientific discipline and university positions as explanatory control variables in our research to identify the effects of these variables on the engagement or scientists with research commercialisation. Based upon our theory in **section 5.1** we hypothesise that RC of a university can be determined by RC involved scientists, their drivers and the university IP regimes as in:

(5.1)
$$RC = \sum RC_i = (C + \alpha. A_i + \beta. X_i + \gamma. D_i + \delta. UP_i + d. Driver_i + t. IP regime type_i + \xi_i + error term)$$

where RC is the research commercialisation of an individual scientist i (i= 1....n). So, RC_i is the sum of the *control* variables Age (*A*), Gender (*X*) discipline (*D*) and university position (*UP*), plus *model* variables Drivers (*D*) and IP regimes types (*IP regime type*) plus random drivers, random IP regime types and individual (ξ) effects of all scientists involved.

An online survey was carried out to investigate which of the studied drivers motivate scientists to engage in IPR-based research commercialisation at universities in countries in Europe and under which university IP regimes. At first, interviews with 25 individual scientists were held to ensure that the format of the survey enabled appropriate data acquisition and collection.

Then a questionnaire was developed which contained four main sections for the acquisition of data at individual and organisational level:

- 1) Scientists' drivers that motivate them to engage in research commercialisation, their actual engagement with RC and their time allocation for the commercialisation of their scientific research results;
- 2) Regulations on IP use and IP ownership at their university and the importance of patents for commercialisation of research and their university career;
- Types and quality of support facilities for the commercialisation of research results at university TTOs;
- 4) Individual background information of the scientist (age, gender, university position, scientific discipline).

All questions in the survey covered a time period between the 2010 and 2015. Using the Survey Monkey platform for electronic administration of response data, the questionnaire was sent to scientists working at some 150 universities in thirty countries in Europe and not to TTO staff, deans or directors. During the survey period, scientists received five follow-up messages between November 2015 and March 2016, with an additional message and the report with summarized results in June 2016.

In this survey we follow the same methodology described in **chapter 4**. Assuming that most research commercialisation activities e.g. patenting are carried out by- and can hence be associated with numbers of PhD students and (associated/assistant) professors (Giuri et al., 2007), we quantified the size of this specific target audience in Europe. With a total population in the EU in 2010 of approximately 508 million persons and considering that some 0,2 % of them received an education at PhD level (Eurostat³⁷), the potential size of the target audience of scientists consists of some 1 million scientists. With a confidence interval of 95% and an accuracy rate of 2%, a minimum sample size (n) of 2, 396 scientists can be used to assure representativeness of data acquisition in this survey (Brian and Jenkins, 2013).

Email addresses of European scientists in all disciplines were randomly selected using the *Web* of Science database at the Centre for Science and Technology Studies (CWTS) of the Leiden University in The Netherlands. Survey participation was voluntary, anonymous and respondents did not receive financial compensation. Data from some 1, 000 respondents were excluded due to too late delivery or retirement while some 300 respondents opted-out. Based upon delivery data of email including the questionnaire, we assume that at most some 30, 000 scientists could participate in the survey. As we had no formal relations with European scientists we anticipated a high non-response rate.

At the close of the survey we received responses (mostly fully filled-out questionnaires) from 2, 665 scientists working at 148 universities in Europe. The response rate of 8,9% is low but exceeds the threshold with a minimal sample size of 2, 396 persons to produce representative

³⁷ <u>http://ec.europa.eu/eurostat/data/database</u> accessed in 2016

data about scientists at universities in European countries. Using the data of control variables (e.g. age, gender, disciplines, positions) on the individual background of the respondents in the four categories of university IP regimes, we were able to compare these variables with open accessible data about university personnel from different university databases and sources^{38,39,40,41}. To verify our data on age and gender of scientists we also used another open source (OECD statistics)⁴². Comparing the availability of data of the control variables (e.g. participants with university positions as PhD students, postdocs, or in disciplines like engineering, earth sciences etc.) of respondents in our survey with scientists' data- available from described open-accessible data sources-we found that they match at an acceptable level. Therefore, we assume that acquired data from survey respondents do not differ significantly from the data from non-respondents and are of the opinion that the acquired data per university IP regime can be regarded as representative and may be used for statistical analyses. In the statistical analyses, the survey data will be processed at an aggregated level of countries, university IP regimes and scientists' drivers.

In addition to an analysis of the survey data, we present four university cases which illustrate the associations between their university IP regimes and the academic engagement of their scientists with RC on the one hand, the levels of academic patenting and creation of spin-offs on the other hand.

5.3. Results

The information from 2, 665 scientists working at 148 European universities (in 27 EU member states including the UK, Norway and Switzerland) has been validated and university IP regimes have been classified according to their IP regimes at country (Appendix A). Table 5.2. shows the summary statistics of responding scientists in terms of engagement with research commercialisation, patenting and creation of spin -off companies as presented by the control and model variables. We observe that the majority of respondents are older than 35 years, male and have a position as associate or assistant professor and work in the medical, life sciences and health, engineering or natural sciences. Irrespective of their drivers and the IP regime of their university some 30% of respondents has been engaged in various forms of research commercialisation (e.g. contract research, cooperation with the industry, consultancy, patents, spin-offs).

Some 60% of scientists spend 10-25% of their time on joint- research with the industry and contract research at a university, while 45% spend more than 25% of their time on these RCactivities. Interestingly, we found that patent awareness amongst scientists in all disciplines is above 80%, that 60% of scientists found patents important for the commercialisation of their

accessed in 2016

accessed in 2016

³⁸ For the EU 'full service' IP regime type, see: <u>Dutch universities</u> accessed in 2016 accessed in 2016

 ³⁹ Idem, for the 'Italian' type, see: <u>Italian universities</u>
 ⁴⁰ Idem, for the EU 'optional service', see: <u>Finnish universities</u>

⁴¹ Idem, for the 'Swedish type', see: <u>Swedish universities</u>

⁴² OECD statistics indicator D 5, see: Education indicators (2016)

Table 5.2Summarised statistics43about European scientists' engagement with
research commercialisation, patenting and spin-offs (2010-2015)

	Scientists		Scientists engaged with Research	Patenting scientists	Scientists engaged with IP-based
			Commercialisation	serentists	spin-offs
	Numbers	(%)	(%)	(%)	(%)
Total	2,665	100			
Scientists involved in RC Patent filing scientists Scientists involved with spin- offs	845 426 227	31.7 16.0 8.5	31.7	16.0	8.5
Variables					
1.Age					
< 35 years 35 -50 years >50 years	573 1, 101 991	21.5 41.3 37.2	25.1 34.2 33.2	8.5 19.3 20.3	
2.Gender					
Male Female No information provided	1532 631 502	57.5 23.7	37.1 27.6	21.2 12.7	
3.Scientific disciplines					
Earth Engineering Mathematics and computer	94 504 218	3.5 18.9 8.2	28.7 45.4 31.7	5.3 26.8 7.2	5.3 12.5 9.2
Medical or Life sciences and health Natural Social, economic and humanities	810 453 134 452	30.4 17.0 5.0	32.5 31.6 20.9	18.4 24.1 0.0	5.5 12.2 2.2
4.University positions	432	17.4	17.2	3.9	1.7
PhD student Post doc Associate or assistant professor Professor Other No information provided by respondent	156 496 765 582 202 464	5.9 18.6 28.7 21.8 7.6 17.4	13.5 26.0 34.9 46.6 33.7 16.8	4.5 11.5 18.3 29.4 19.8 3.5	3.2 5.6 6.7 12.2 0.0 3.7
5.Scientists' drivers					
Recognition Research Entrepreneurship Other Not applicable according to respondent	223 1,006 330 53 1,053	8.4 37.7 12.4 2.0 38.3	44.1 48.0 55.0 56.7 6.6	19.0 22.9 32.2 11.4 3.5	5.0 9.4 27.0 0.0 2.7
6.University IP regimes types					
EU full service Italian EU optional service Swedish No information provided by respondent	1, 128 135 461 154 787	42.3 5.1 17.3 5.8 29.5	39.0 32.6 30.8 33.7 20.3	21.3 17.0 17.1 18.2 7.9	9.4 10.4 6.9 14.9 6.7

⁴³ The survey with the original dataset has been deposited at the repository of the Royal Netherlands Academy of Arts and Sciences, and data are open accessible at <u>https://doi.org/10.17026/dans-xgg-r2nu</u>

present research and 50% for their careers. On average, 16% of the scientists have filed patents since 2010 and 8% has been engaged in the of an IP-based spin-off. Some 40% of the scientists found the drivers as formulated not applicable for them and that same percentage responded that their involvement with research commercialisation was research-driven. We found that some 40% of the scientists work at universities with national legislation on university IPR ownership on research results and providing obligatory research commercialisation services at a centrally located TTO (i.e. 'EU Full service' type). Some 55% of scientists contacted their university TTO for legal, business or financial assistance and in case of spin- off creation. In general they found the quality of received TTO services satisfactory, but could use more assistance with new business development.

Looking at the number of scientists that are engaged with research commercialisation and patenting, the relationships with their drivers and university IP regimes become evident. This is not immediately evident for IP-based university spin-offs that apparently can only be related

	Number of scientists	RC engaged scientists		Patenting scientists		Scientists engaged in spin–offs	
		(%)		(%)		(%)	
University IP regimes			RC engaged scientists		Patenting scientists		Scientists engaged in spin–offs
EU 'full service'	1, 128	39.0		21.3		9,4	
Italian	135	32.6	Rank correlation	17.0	Rank correlation	10,4	Rank correlation
EU 'optional service'	461	30.8	coefficient	17.1	coefficient	6.9	coefficient
Swedish	154	33.7	0.186 (***)	18.2	0.113 (***)	14.9	0.036
Not classified	787	20.3		7.9		6.7	
Scientists' drivers							
Recognition	223	44.1		19.0		5.0	
Research	1,006	48.0	Rank correlation	22.9	Rank correlation	9.4	Rank correlation
Entrepreneurship	330	55.0	coefficient	32.2	coefficient	27.0	coefficient
Other	53	56.7	0.411 (***)	11.4	0.424 (***)	0	0.301 (***)
Not applicable for scientist	1,043	6.6		3.5		2.7	

Table 5.3 Relationships between university IP regimes, scientists' drivers and their engagement with research commercialisation (RC), patenting and spin-offs

N = 2,665 Bivariate Spearman rank correlation analyses ^(***) highly significant at 0.01 level (two- tailed)

with scientists' drivers but not with the university IP regimes. Therefore, we assume that the differences in both the university IP regimes and scientists' drivers on the one hand, may be

associated with different levels engagement in research involvement, patenting and spin-off creation on the other hand. **Table 5.3.** shows the results of statistical bivariate correlation analyses of the data for the variables used. We observe that the associations between university IP regimes and the engagement of scientists with research commercialisation and patenting are significant, positive and small. The association between university IP regimes and the engagement of scientists' drivers that motivate scientists to engage in RC, patenting and spin-off creation are all significant, positive and quite large. We observe that the rank correlation coefficients of these driving forces are 2-8 times larger than those of the university IP regimes. These results imply that individual drivers that motivate scientists to engage in the commercialisation of their research are much more important than external university IP regimes implemented by national law and regulated via obligatory TTO services.

Due to anticipated endogeneity effects between the control variable age and the model variable university position, the former was not included in subsequent multiple ordinal regression analyses. Given the large number of universities and European countries that are involved in this study, multiple ordinal regression analysis techniques are allowed (Brian and Jenkins, 2013). These regressions were run to obtain more detailed information about the significance of all model variables that can be potentially correlated with scientists' involvement in research commercialisation (equation RC (5.1). The model fit was not violated (at a pseudo 'Nagelkerke' $R^2 = 54\%$) indicating the percentage of locations of variables that could be accurately predicted in this model.

Figure 5.1. shows which of the 17 examined variables, projected on the x-axis, attributes most to RC engagement of scientists in Europe, projected on the y-axis, and hence to the commercialisation of scientific research. Here, it becomes clear that the personal drivers of



Figure 5.1. Scientists RC engagement in relationship with 17 variables

scientists are by far most dominant in relationship with their RC engagement. Studied variables are projected on the x-axis and the percentages of RC engagement, patenting and spin-off creation are projected on the y-axis. The relationships between studied variables and RC engagement, patenting and spin-off creation are shown in **figures 5.2.- 5.9**. The statistical analysis of the relationships between the variables and the RC output (engagement, patenting and spin-off creation) is presented in **Appendix B**.



Figure 5.3. Scientists' RC engagement (%) vs. their university IP regimes



Figure 5.4. Scientists' RC engagement (%) vs. disciplines (D)



Figure 5.5. Scientists' RC engagement (%) vs. university positions (UP)



(D)

- 1. Sociology, economy and humanities, 2. Earth sciences,
- 3. Natural sciences, 4. Mathematics and ICT,
- 5. Medical and Lifesciences and Health, 6. Engineering



Figure 5.6. Patenting (%) by disciplines (D)



Figure 5.7. Patenting (%) vs. university positions (UP)



Figure 5.8. Spin-off creation (%) vs. disciplines (D)





(D)

1. Sociology, economy and humanities, 2. Earth sciences,

3. Natural sciences, 4. Mathematics and ICT,

5. Medical and Lifesciences and Health, 6. Engineering

(UP) 1. PhD student, 2. Post doc, 3. Associate or assistant professor, 4. Professor

Considering the results in figures 5.1.-5.9. and the statistical analyses of the survey data (Appendix B) we acknowledge that scientists' RC can be significantly associated with the four examined model variables (e.g. scientists' drivers, university IP regimes, disciplines and university positions). Above all, figure 5.1, shows that entrepreneurial professors in the engineering sciences, working at universities with an 'EU full service IP regime' show the highest levels of RC engagement, patenting and creation of spin-offs. Data in figures 5.2 and 5.3 confirm that RC engagement of scientists is significantly associated with studied model variables (three 'driving forces' that motivate scientists and four university 'IP regimes'). Figures 5.4, 5.6 and 5.8 show that the scientific disciplines (D) of surveyed scientists are significantly associated with their research commercialisation, patenting and the creation of spin-off companies. Engineering scientists are most RC engaged, involved in filing of patents and creation of spin-offs (respectively 45%, 27% and 13%). Figures 5.5, 5.7 and 5.9 show that RC engagement, patenting and the creation of spin-off companies are significantly associated with the university positions (UP) of scientists. Professors are significantly more RC engaged and involved with patent filing and spin-off creation (respectively 47%, 29% and 12%) than PhD students (respectively 14%, 5% and 3%).

Table 5.4. gives more detailed information about the data of studied model and control variables in this chapter as university case studies. In these studies, data from four well known universities in Europe (e.g. Karolinska Institutet, Politecnico di Milano, Aalto Univerity and National Universiversity Galway) are presented as 10 indicators, enabling a comparison of and explanation for the impact of their four, distinct university IP regimes on the RC output of the university. Due to the low numbers of responding scientists working at these universities, we cannot claim that these cases are representative.

Table 5.4.	Relationships between research commercialisation, studied variables and other indicators at four European universities and their IP regimes (%)

Variables and other indicators	University IP regime type (*)			
	EU full service	<u>EU optional</u> <u>service</u>	<u>Italian</u>	Swedish
1. University (country)	National University Galway (Ireland)	Aalto University (Finland)	Politecnico de Milano (Italy)	Karolinska Institutet (Sweden)
2. University IP ownership by law	Yes	Yes	No	No
3.Central TTO and obligatory services for scientists	Yes	No	Yes	No
 4. Scientists per discipline - Earth - Engineering - Mathematics - Medical - Natural - Social 	39 6 44 11	- 70 4 9 17 -	10 71 10 10 -	- - 90 - 10
5.University IP policy	Commercialise or license	IP is used for research and innovation services	Transfer and use by industry	No reliable data form website or annual reports
6. Scientists' drivers : - Recognition - Research - Entrepreneurship - Other	33 33 33	80 20	50 50	43 14 43
7.Scientists that have contacted the TTO for RC	71	65	67	18
 8. Kind of TTO support asked for by scientists; Patenting Business support Funding research Spin off agreements Legal Licensing 	38 38 25	63 13 25	33 - - 33 33	Unknown
9. Patenting scientists	33	44	28	0
10. Scientists involved with spin-offs	19	9	24	5
RC engaged scientists (%)	67	61	52	19

See table 5.1 for further definitions (*)

Responding scientists from the Karolinska Institutet in Sweden attribute a lower value of importance to IP for their careers, have no obligatory contacts with a TTO to file patent applications, but have some time to develop a spin-off company based upon the IP that they appropriate based upon their own research. Responding scientists at the Politecnico de Milano in Italy found that patents are important for their careers and for their present research. The majority of scientists responded that they have enough time for spin-off development and although they are obliged to contact the TTO to file patents, they appreciated the TTO services for commercialisation of their research as `good value for money`.

Comparing the data of scientists in Sweden with those at Aalto University in Finland, a country where universities legally own the IPR on all research and where the university has an IP regime that provides 'optional' TTO services, we observe higher levels of engagement with research commercialisation and patenting. We compared the data provided by scientists at Karolinska Institutet with data from responding scientists at the National University of Ireland at Galway and observed that RC engagement and academic patenting are higher at the latter institute.

Looking at the information and data in these university case studies on RC engagement for indicators 6, 7, 9 and 10 (respectively scientists' drivers, scientists who contacted the university TTO, patenting scientists and scientists involved with spin-offs) in line with their IP regimes, we find a general confirmation of the observations and results from the earlier statistical analyses in this paragraph.

As Irish universities generally rank high in Codes of Practice for Technology Transfer of the EU (Arundel, 2013) the TTO of the National University of Ireland at Galway (NUIG) appears to be contacted by the majority of the university scientist's. The number of NUIG's patenting scientists is twice the European average of 16% and their engagement with the creation of spin-off companies is more than double the EU average of 8 %. On the other end of the spectrum, Swedish universities rank low in the EU Codes of Practice for Technology Transfer (Arundel, 2013). Without a formal IP policy or a centralized TTO at the Karolinska Institutet, we found that scientists are less RC engaged compared with the European average, filed no patents but are engaged with the creation of spin-offs at 63% of the European average.

5.4. Limitations

This research has been focussed on IP-based research commercialisation only. Since knowledge and technology transfer can occur outside the IP system (Fini, Lacetera and Shane, 2010), we included other pathways of research commercialisation (e.g. joint research, contract research, consultancy, training of company employees, attendance to conferences) in our survey, but did not describe those results in-depth in this chapter. As researchers in social sciences or economics do not perceive those pathways of RC as a form of research 'valorisation' (De Jong, 2015), it is interesting to observe that our study shows that at European level at least some 25 % of responding sociologists and economics have been engaged in other

RC pathways than patenting or spin-off creation (e.g. consultancy, conferences, contracts with the industry).

5.5. Conclusions and discussion

Our research shows that:

- a. In general, we found that some 32% of European scientists are engaged with several pathways of research commercialisation, 16% with patenting and 8% with the creation of spin- offs;
- b. Research commercialisation can be statistically significantly associated with the drivers of scientists that motivate them to engage in the commercialisation of their research. Entrepreneurship-driven scientists are more engaged with research commercialisation (55%), patenting (32%), and spin-off creation (27%) than scientists driven by recognition or research;
- c. Research commercialisation can be associated with the IP regimes of universities. At universities with EU `full service' IP regimes more scientists (39%) are engaged with research commercialisation which is significantly higher than research commercialisation engaged scientists at universities with other IP regimes;
- d. The *individual* drivers of scientists, that motivate them to engage in the commercialisation of their research, are significantly more important than the *external* (institutional/organisational) university IP regimes of the university where they work.

This research on scientists' individual engagement in research commercialisation (RC) is is the first study that generates cross-national data enabling analyses at both scientists' level and pan-European level. We ensured the acquisition of an unbiased data set, because we surveyed scientists from all disciplines and respondents participated on a voluntary and unpaid basis. Although the response rate in the survey was low we have shown that the sample size of respondents was large enough and thus representative for the target audience of European scientists. For more detailed cross-national comparison using university data larger sample sizes of university scientists are needed.

As the questionnaire of our survey has not been sent to TTOs, their employees, deans of faculties or boards of directors, the information and data in our survey might not match with collected data by the TTO network organisations like ASTP-Proton. Applying a bottom-up approach in our research methodology we found significant differences in research commercialisation that can be associated with the drivers participating scientists. Our findings may be compromised since more than 75% of participating scientists work in the engineering or life sciences. A minor percentage of 20% of sociologists, economists and scientists from

non-technical disciplines could mitigate this bias. Our findings that research- and entrepreneurship-driven scientists are above average engaged with patenting, are in line with studies in Sweden and the UK (Hvide and Jones, 2016, Smith et al., 2010, Lam, 2010) but contrast research data from Germany (Grimpe and Fier, 2010). In the latter case, the 'professors privilege' was abolished and academic patent applications dropped significantly (Czarnitsky et al., 2015).

Our finding that some 30% of the scientists at universities in 30 countries in Europe is engaged with the research commercialisation of their research is comparable with the levels of 25% of RC-engaged scientists found in US and Japan (Nagaoka and Walsh, 2009) and in Western European countries (Giuri et al., 2007). The average 16% of European scientists that have filed academic patents is in line with other research, here our findings on academic patenting by scientists are in line with previous research showing that many academic inventors acquired their prolific IP behaviour prior to their academic career when working in the industry or private sector (Audretsch and Göpteke- Hultén, 2015 and Lissoni, 2012). However, in our research we observed significantly higher levels of academic patenting by scientists at universities with an 'EU full service' IP regime, especially for entrepreneurship-driven scientists, at senior university positions in the engineering and life sciences. At some universities (e.g. in Italy and Ireland) these higher rates of academic patenting can be attributed to particular IP policies that stimulate scientists to file patents as an important incentive for their scientific career. The level of patenting by European scientists is some 20% lower than for US scientists and the average age of European scientists that file patent applications is higher than observed for Japanese scientists (Nagaoka and Walsh, 2009).

If the creation of spin-offs is not an integral part of the mission of the university (Richards, 2012), specialised courses on technology-based entrepreneurship provide opportunities for students and PhD students to team up with (associate) professors create new IP-based ventures (Hartmann, 2014). The majority of the eight percent of European scientists, who are involved with the creation of a spin-offs in this research, found TTO support to acquire financial means and/or business development insufficient. Only Italian scientists were satisfied about the time that their universities allowed them to develop a spin-off company based upon their own IP. In Sweden, a country where the professors' privilege is in force, some 15% of the scientists is involved with the creation of spin-offs, which is almost twice the EU average. With a population of some 10 million inhabitants and a limited number of multinational firms, Swedish policy advisors advocate that future economy growth depends on successful start-ups. Free courses on entrepreneurship, soft funding for start-ups and patent applications have attributed to the recent growth of a number of successful start-ups, like Skype and Spotify (Åstebro et al., 2012; Techworld⁴⁴). The opening of a dedicated health incubator at Lund University (Fierce Biotech, 2015) presents another example of Swedish economic development policy that deviates from IP legislation and TTO regulations in other EU countries (Geuna and Rossi, 2011). However, unaligned or non- transparent university TT policies about IP ownership and/or shares in the new venture may results in time consuming negotiations

⁴⁴ <u>https://www.techworld.com/</u> Data about Skype and Spotify, accessed in 2015 and 2016

between a TTO and the founder of or investor in a university spin-off and are one of the causes that reduce the number and delay the growth of start-ups (Technopolis, 2015).

The positive, large associations between scientists' drivers to engagement in the creation of spin-offs compared to an insignificant association between the university IP regime and the number of scientists that are engaged with the creation of spin- offs, means that spin-off creation is solely determined by the first factor and not by the latter. Within the body of literature we have not identified identical findings by other researchers.

Future research on how scientists' drivers and university IP regimes can affect research commercialisation would greatly benefit from more cross-country and continental comparisons (e.g. Australia, Brazil, China, EU, Japan, South-Korea, Russia, and USA). Here, it will be essential to use standardized formats for data collection and include data on the financial budgets for scientific research. At European level an attempt to combine the methodology and data from this research with available data recorded by university TTOs in Europe (e.g. ASTP-Proton) using interviews with deans and research coordinators could be a first attempt in that direction.

Finally, the effects of a reduction in research funding and anticipated, stricter regulations for the interaction between universities and the private sector (Martinez, Lissoni, Sanz-Menendez, 2016) on academic engagement with RC provide interesting avenues for research on this topic in future.

University IP regime types in European countries⁴⁵ Appendix A

	Obligatory RC services for scientists at centrally located TTO			
University IP ownership on academic research regulated by national law	YES	NO	No information	
YES	<u>EU 'full service' type</u> Austria, Belgium, Czech Republic, Denmark, France, Ireland, Spain, Netherlands and United Kingdom, plus Norway	EU 'optional service' type Finland, Germany, Greece , Hungary, Poland and Portugal		
NO	<u>Italian type</u> Italy	<u>Swedish type</u> Sweden		
Information not complete or missing	Switzerland	Bulgaria, Croatia, Cyprus, Estonia, Iceland , Latvia, Macedonia, Romania, Serbia and Slovakia	Luxembourg	

Appendix B Statistical analysis of relationships between RC engaged scientists and four variables

	Number of RC engaged scientist	RC engaged scientists (%)
Variables		
1.Scientists' drivers		
Recognition (**)	223	44.1
Research (**)	1,006	48.0
Entrepreneurship (**)	330	55.0
2.University IP regime type		
EU 'full service' (**)	1, 128	39.0
EU 'optional service' (**)	135	32.6
Italian (**)	461	30.8
Swedish (**)	154	33.7
3.Discipline		
Social, economy and humanities (**)	134	20.9
Earth (**)	94	28.7
Natural (**)	453	31.6
Mathematics and computer science (**)	218	31.7
Medical and Life sciences and Health (**)	810	32.5
Engineering (**)	504	45.4
4.University position		
PhD student (***)	156	13.5
Post doc (***)	496	26.0
Assistant or associate Professor (***)	765	34.9
Professor (***)	582	46.6
Age	Control variable	
Gender	Control variable	
$(**) = -i = -i f_{+} + 0.05$ $(***)$	- highly significant at 0.01	4

(**) = significant at 0,05 (***)= highly significant at 0.01

 $^{^{\}rm 45}$ involved in this study, status June 2016

Chapter

The value of academic patents for university spinoffs: A case study of gene therapies ⁴⁶

Abstract

This chapter describes a case study with indicators to estimate the value of academic patents. Within the sector of life sciences and health, we examined the niche market of patented academic gene therapies resulting from scientific research, in a longitudinal study from 1995- 2015. Market authorisation for the use of gene therapies by regulatory organisations has been very limited. In a patent cluster of patented gene therapies, filed in the year 1995, we found that: a) 53% of these patents have been renewed until their maximum patent term of twenty years, and b) 49% of the granted patents have been licensed. Statistical analyses show a significant correlation between gene patent renewals and the number of citations in future patent applications by third parties to these gene patents. Our data suggest that both patent terms and the number of patent citations can be used as indicators to determine the value of patented gene therapies invented at universities.

A market capitalisation analysis of Crucell, a spin-off from the Leiden and Utrecht Universities in the Netherlands, shows that the number of patent citations by third parties to their priority patent application EP 0833934, can be used to predict the value of this company with a time lag effect of one year.

⁴⁶ This chapter was published as:

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6.1. Introduction

The number of company patent applications or granted patents in a particular sector can be correlated with their R&D expenditures and innovativeness (OECD, 2011). Companies usually file and renew their patents only in those countries where they expect that customers will use their appropriated inventions and healthy gross margins on products sold or license fees are expected and realised.

The monetary value of a patent is often defined as the sum of revenues of sold volume of patented protected products during its' patent term (incl. license revenues) minus the costs to file and renew the patent (Gambardella et al., 2008). Some researchers used patent citations to study the relations between the monetary value of patents, sales and the market value of the patent owner in various sectors of the economy (Harhoff et al, 1999; Hall et al, 2007; Narin et al, 1997). Patent family size and opposition may also be used as indicators to determine the value of patents (Harhoff et al., 2003). Studying patent renewal fees paid for 964 inventions filed both in the USA and Germany, these researchers concluded that patents, renewed to the full term of 20 years, were significantly higher cited. Analysing some 4, 900 R&D projects in the pharma sector, researchers found that a 'one per cent increase of number of citations, corresponds with 0.3% increase in total sales' (Magazzini et al., 2008). Combining market values of 4, 864 publically traded companies in the USA and their granted US patents between 1963 and 1999, in a broad range of industry sectors, it became evident that patent citations provide a useful means to estimate the market value of a company (Hall et al., 2005). These researchers concluded that 'an extra citation per patent boasts the market value by 3%' and 'self-citations appear to be more valuable than external citations by third parties'. On a global scale, pharma and biotechnology companies that manage their patent portfolios well have become very successful (Zechendorf, 2011; Pugatch et al., 2012).

Research on the monetary value of patents has focused on the automotive, chemistry, electronics, and pharma sectors, excluding biotechnology (Trajtenberg, 1990; Narin et al., 1987; Carpenter et al., 1981). For academic patents that can fill the product and process pipelines of companies and become successful innovations (Andries and Faems, 2013), we notice here an important knowledge gap. Since market values of companies in the USA and the EU can be correlated with the numbers of citations to their patents (Hall et al., 2007), investors are interested in companies with many, highly-cited cited patents, including those from university spin-offs. Thus, following research questions will be addressed:

- Can we identify indicators that determine why patent terms of academic patents have been extended for the maximum term of 20 years?
- Can the monetary value of academic patents be related to these indicators?
- How to determine the financial value of spin-offs which commercialise academic patents?

6.2. Patented academic gene therapies in the life sciences sector and their value

In the sector of the life sciences and health, biotechnology inventions have contributed to significant improvements in e.g. plant breeding, food supply, manufacturing of drugs and health care (Castle, 2006). Here, modern biotechnology can be defined as an array of technologies that uses recombinant DNA (rDNA) in biological systems for practical means (Torrance, 2014). Biotechnology can also enable gene therapies by the delivery of nucleic acid polymers into patients' cells as a drug to treat a disease, or as medical preparations containing genetic natural material inserted into cells to treat genetic diseases in persons. Considering that some 4% of the global population has genetic disorders (Alberts et al., 2012), gene therapies hold great promise for medical use.

In the wake of university spin-off biotechnology companies (e.g. Genentech) and the development of the biotechnology sector in the USA, discussions arose about the ownership of scientific knowledge developed with funds from governmental research organisations (e.g. National Institutes of Health, NIH), and the role and implications of IPRs for the commercialisation of academic inventions (Regents of UCLA, 2001). Since the founding of these companies in the 1980s with their potential cures for patients with genetic malfunctioning organs (e.g. Amgen, Chiron), numerous inventions have been patented in domains like cancer treatment, immunology and the production of vaccines (Zucker et al., 2002). In this sector in particular, the magnitude of the commercialisation of academic patents, both in the USA and the EU, is evident (Patzelt and Brenner, 2008) and the number of gene patents has been on the rise for many years (Soini et al., 2008). However, the outlook and consequences of patenting DNA and genes for therapies and research are well documented (Dutfield, 2006; Jensen and Murray, 2005). Nowadays, the European Medicines Agency (EMA) receives less than five applications⁴⁷ for gene therapy medical products per year, and so far only Glybera® and Strimvelis® obtained market authorisation⁴⁸.

Given the nature and origin of the companies which commercialise their patented gene therapies, often university spin-offs at campus (Mochly-Rosen and Grimes, 2014; Patzelt and Brenner, 2008) - and the fact that the majority of these patents are university-invented (Sampat and Pincus, 2015; Jensen and Murray, 2005), present an interesting opportunity for an IP landscape case study. Following economic theories (**section 6.1.**), we argue that the monetary value of academic patents can be estimated using similar methodologies as for patents in general (Gambardella et al., 2008; Magazinni et al, 2008; Hall et al., 2005; Harhoff et al., 2003, 1998). Hence, following hypotheses will be tested:

- *H.1.* The value of a gene therapy patent is positively correlated to the number of designated countries in the patent application;
- *H.2.* The value of a gene therapy patent is positively correlated to number of product or process claims in the patent application;

⁴⁷ Personal communication, B. Leufkens, (CBG), 2016

⁴⁸ <u>http://www.ema.europa.eu/GTMP</u>

- *H.3.* The value of a gene therapy patent is positively correlated to the number of licenses for the patent;
- *H.4.* The value of a gene therapy patent is positively correlated to the number of citations (in subsequent patent applications in future) to the patent

Each of these hypotheses will be accepted, if statistically positive correlations at 95 or 99% between the value of the patent and mentioned parameter will be measured or relationships with a R^2 higher than 0.9.

6.3. Methodology and data resources

A global patent analysis of the life sciences and health sector between 1995 and 2005 will be conducted to identify and quantify the numbers of patent applications in the domains of cancer, cardio vascular diseases, medical imaging, immunology, vaccine development and neurodegenerative disorders. The PATSTAT database of the European Patent Organisation and the international patent classification codes for these domains will be used⁴⁹ (**Appendix A**). Based upon the results of this global patent landscape, the most important patentees can be identified and their patent applications can be quantified. This landscape will be used for a patent cluster analysis in the niche market of gene therapies to measure the performance of gene therapy patentees since 1995.

To test our hypotheses, a quantitative, longitudinal analysis of patented gene therapies of companies and research institutes will be conducted in the time period between 1995 and 2015. We will collect data on the patent application routes, patent terms, number of designated countries (or patent family size), number of patent claims, citations and licensees.

The collected data can be used in a patent cluster analysis to identify all patent applications that have been filed in the same year (1995) and within the same patent classification classes (A61K48, C12N7 and C12N15/86) as the patented gene therapy EP 0833934 '*Packaging systems of human recombinant adenoviruses to be used for gene therapy*' of the Dutch spin-off IntroGene/Crucell. Their patented PER.C6 technology has been exploited and managed for the full patent term of 20 years, even after the acquisition of the company by Johnson and Johnson, in 2011. This patent of Crucell (Fallaux et al, 1995) has been selected as a benchmark for this cluster analysis since it has been successfully managed for several exclusive applications in niche markets (e.g. through licenses to Transgene, DSM, Genzyme and research organisations, such as the National Institutes of Health) and was used as a platform technology for the development of vaccines and for future use in immunology.

Searching for the same patent classification codes as EP 0833934 in Espacenet and in EPODOC, similar gene therapy patents that were filed in 1995 could be identified, as well as their applicants. These databases, used by patent examiners at the European Patent Office, also contain bibliographic information and citations to patents and patent applications in over 90

⁴⁹ http://www.epo.org/searching

countries (Hawk IP, 2012)⁵⁰. During the examination process, examiners at a patent office have to identify prior disclosures of a technology describing the claims in the patent application in full or partially, thus revealing documents as the closest state of the art in their search reports. If such documents are found, they are submitted to the applicant of the new patent application and will be cited in future applications for inventions in the same technical domain (Munari and Oriani, 2011). So, the number of times that a particular patent publication is cited in future patent applications can be a used as an indicator of its technical and commercial significance. Once the indicators have been identified that explain why patent holders of gene therapies renew their patent terms untill the maximum patent term of twenty years, the research will continue and study if these indicators can be linked to the market value of the company, using different methods for patent valuation (Harhoff et al., 1999) and the theories for the diffusion of medical innovations (Blume, 2013; Rogers, 2003).

Between 2014 and 2015, interviews with ten stake holders in the Dutch life sciences sector (scientists, academic entrepreneurs, patent attorneys and university TTO officers) were conducted to validate our quantitative findings. Interviews with the original inventors of the PER.C6 technology, IP managers of Crucell, venture capitalists that provided initial financial resources and stock holders were conducted to obtain more background information about the journey from the scientific discovery towards the global exploitation of this patented academic gene therapy.

6.4. Overall results

Figures 6.1.a and 6.1.b show the developments of the numbers of annual gene therapy patent applications and the patent applications in six domains of the life sciences and health that have been filed. These patent applications include all patent documents that were filed via the worldwide (WO/ PCT) and European (EP) application procedures in the domains cancer (36, 375), cardiovascular diseases (3, 261), medical imaging (1, 557), immunology (17, 348), vaccines development against infectious diseases (13, 065) and neurodegenerative disorders (5, 859). For gene therapies patent applications, an increase until 2003 (and a decrease of 64% since 2003) can be observed. In the domains of cancer, neurodegenerative disorders, cardiovascular diseases and medical imaging, the number of applications increases until 2005, but a reduction of applications for immunology (22% since 2000) and vaccines (33% since 2000) took place.

Using the Thomsom Scientific WPI Index, identified patent applications can be converted into the domains of use (**Appendix B**). Within the scope of this research there is a focus on gene therapies related to patent applications in the domains of cancer, immunology and vaccines only. Most gene therapy patent applications have been filed by companies and universities headquartered in the USA, followed by Germany, Japan, United Kingdom, France, Canada, Switzerland, The Netherlands, Sweden and Korea. GlaxoSmithKline, Merck and Bayer were

⁵⁰ http://www.hawkip.com-epodoc

Figure 6.1.a. Annual number of gene therapy patent applications (WO and EP)

Figure 6.1. b. Annual numbers of life science and health patent applications (WO and EP)



the companies that filed most applications followed by a number of biotechnology companies and universities. Especially in the domain of vaccine development, high percentages of technologies using genetically-modified organisms are found. Between 1995 and 2005, on average only 1.8% of the patents in the domains of cancer, immunology and vaccine development are gene therapy related (see page 129, table B.3 in Appendix B⁵¹). Based upon this percentage and the total numbers of patent applications in these domains, an average of some 120 unique gene therapy inventions is expected to be patented per year. Figure 6.1.a shows an annual number of 1, 768 of WO and EP patent applications in 1995, which implies that e.g. 120 unique gene therapy inventions have become registered in some 15 countries (= 1, 768 / 120). Table 6.1 shows a worldwide patent cluster of 93 gene therapies which have been classified in the same patent classification codes as EP 0833934 of Introgene/Crucell (A61K48, C12N7 and C12N15/86) and filed by (university) spin-offs in the year 1995, according to the internal Epoque and open access database Espacenet of the European Patent Office⁵². Some 50 % of these patents can be classified as academic patents. Out of these 93 patent applications 76 have been by several patent granting organisations, and 37 have been licensed to third parties, e.g. Oxford Biomedica Ltd. (eleven gene therapy patents from Chiron-Viagene Inc.) and the National Institutes of Health in the USA (five gene patents from US universities and three from companies).

Table 6.2. shows the results of the analysis of the patent cluster, indicating that 53% of the patents have been granted and renewed until the maximum patent term of 20 years. Additionally 28% have been renewed for more than 15 years. In total, more than 80% of gene therapy patents were renewed for more than 15 years, while 37 of the total of 76 granted patents have been licensed to third parties. Plotting the patent terms (in years of validity) of the granted patents against the actual numbers of patents granted (parameter A), their percentage of licenses (parameter D) and the number of citations (parameter E) significant differences are observed. The data in this table provide evidence that more patent holders renew their patents

⁵¹ http://www.epo.org/searching

⁵² http://www.epo.org/searching

Applications by compan	iies	Academic patent	Inventors mentioned in 93 patent applications		patent Inventors mentioned in 93 pater applications		Licensees of 37 grantee patents ^(*)	l gene
Chiron–Viagene	17	0	H. Gruber	16	Oxford Biomedica Ltd.	29		
American Cyanamid	6	0	D. Jolly	11	National Institutes of Health	26		
Transgene	5	60	J. Barber	7	East Virginia Medical School	8		
Genvec	5	40	1.Koveski	7	GBP IP	5		
Canji	4	0	A.McCormick	4	Glaxo Welcome	3		
Genetic Therapy	3	100	P. Klatzmann	4	US Health	3		
Cell Genesis	3	100	W. Zhang	4	Texas Cancer Centre	3		
Introgene/Crucell	1	100	S. Woo	4	Others	23		
University Paris	4	100	Others	43				
University Texas	4	100						
University California	3	100						
Baylor College of	3	100						
Medicine								
Others	43	47 (**)						

Table 6.1. Applicants, inventors and licensees of gene therapy patents, filed in 1995 (%)

N = 93

^(*)Organisations can in- license more than one patent

(**) Based upon data from university spin-offs

Table 6.2.Patent terms (validity in years) vs. parameters A, B, C, D and E of gene
therapy patents filed in 1995

Paramet	er Patent terms in years:	20	15 - 19	10-14	< 10
A.	Number of granted patents (N=76)	40	21	12	3
-	US priority (60)	32	18 (*)	10 (**)	0 (**)
-	French priority (9)	3	2	1	3
-	UK priority (2)	0	1	1	0
-	EP priority (2)	2	0	0	0
-	Denmark priority (1)	1	0	0	0
-	German priority (1)	1	0	0	0
-	Israëli priority (1)	1	0	0	0
B.	Avg. number of countries	35	30	42	33
C.	Avg. number of claims	31	21	18	24
-	Patents with product claims	36	2	0	0
-	Patents with process claims	35	15	7	4
D.	Number of license agreements	21	11 (**)	5 (**)	0 (**)
E.	Avg. number of citations	53	41 (*)	21 (**)	6 (**)

Significant at (*) p= 0.05 and (**) p= 0.01

 R^2 (patent terms – license agreements) = 0.96, R^2 (patent term – average number of citations) = 0.99

for more years when their patent is: a) granted in the USA, b) licensed to third parties and c) have been cited more frequently.

In addition to the significant differences in patent renewal payments for patents filed with a priority in the USA, most of the patentees also decided to maintain their patent in the UK, France, Germany and Japan. No significant differences were found for patents that had a priority filing in other countries than the USA and were subsequently renewed by their patent holders for the different sets of time frames as indicated. Based upon this evidence and statistics from **table 6.2**. hypotheses *H.1.* stating that he value of a gene therapy patent is positively correlated to the number of designated countries in the patent application and *H.2.*, stating that the value of a gene therapy patent is positively correlated to number of product or process claims in the patent application, have to be rejected. On the other hand, *H.3.* stating that value of a gene therapy patent is positively correlated to the number of a gene therapy patent is positively correlated to the number of a gene therapy patent is positively correlated to the number of licensees, and *H.4.*, stating that the value of a gene therapy patent is positively correlated the number of citations (in future patent applications) can be accepted.

6.5. A case study about patent citations and market capitalisation for a university spin-off

Here, we present a case study about the development of Dutch spin-off company Crucell that exploited a patented gene therapy since the mid 1990s. **Table 6.3.** shows the number of citations of the Introgene/Crucell US patent US6033908 in subsequent patent applications (including 69 self-citations by Introgene and Crucell subsequent patent applications). The notion that the proportion of self-citations to all citations to the patent of a spin-off company can be used as an indicator to determine the value and the acceptance of a gene therapy then becomes apparent. To prove this hypothesis, the number of self-citations in three specific gene therapy patents filed in 1995 as percentage of the total number of citations was compared with

Company	Patent	Number of citations	Number of self- citations	Name
		(A)	(B)	
Patents filed in 1995				
IntroGene/ Crucell	US6033908	206	69	PER.C6®
Transgene	US6040174	269	29	
Reference patents				
Stanford/ Boyer	US4237224	401	58	rDNA process
Idem	US4468464	124	9	rDNA product
Cetus/ Mullis	US4863202	6, 578	11	PCR®

Table 6.3.Comparison of numbers of (self-) citations in subsequent patent
applications to patents filed in 1995 with three reference patents

data from famous global patented innovations. As a point of reference, the analogy between patent citations and citations to papers can be used. Breakthrough discoveries will be cited after publication in a scientific paper by peers while the concordant invention might be patented. It is expected that, over time, important patents (like publications) have a higher chance to be cited by future patent applicants since they comprise the most relevant state of the art. The priority patent of Introgene/Crucell (**figure 6.2.a.**) has also been cited by its spin- off company Galapagos in 1999, while in 2009 and 2010 the number of self-citations and citations by third parties reached a higher level again, prior to the acquisition of Crucell by Johnson & Johnson in 2011.

Following citations of the famous rDNA process patent US4237224 of Boyer and Cohen of Stanford/ Genentech (**figure 6.2.b**), it can be observed that after the filing date of this patent the company applied for future patents citing this original patent, as well as did third parties. During the mid 1990s and still after the expiration of the patent, it is cited in patent applications by third parties. Since the patented rDNA process and the PCR technology (see **table 6.4**) have been more frequently cited than the patented PER.C6 technology, peer inventors value those patents more. The need for an introduction of a correction factor over time, thus reducing the importance of self-citations in patents of a start-up company, becomes evident.

Figure 6.2.a. Number of citations to the US6033908 of Crucell in other patent applications (per year)





Data in **table 6.1.** show that Chiron-Viagene Inc. was the largest applicant of gene therapy patents in 1995. The number of patent applications by Chiron-Viagene Inc. and biotechnology spin-off company Introgene/ Crucell in the domains of cancer, immunology and vaccines between 1995 and 2005 are presented in **table 6.4**. It is obvious that only in the domain of vaccine development Crucell might be considered a serious competitor to Chiron-Viagene Inc.

	Domain	Cancer	Immunology	Vaccine
Company				
Chiron-Viagene Inc.		182 (27)*	169 (9)	119 (10)
Introgene /Crucell		23 (-)	37 (76)	45 (39)

Table 6.4.Number of gene therapy patent applications per company filed between
1995 and 2005 in three domains

* (N) = world ranking patent applicants

Figure 6.3. presents a comparative analysis of the patent applications by Introgene/Crucell and Chiron-Viagene Inc. in 1995 demonstrates the different characteristics of their patent portfolio. The analysis shows that this single patent of Introgene/Crucell has been cited in 206 subsequent patent applications, while the twelve patents of Chiron-Viagene Inc. have been cited on average in 16 applications between 1995 and 2015.

Figure 6.3. Comparison of the number of citations of one patent from Crucell and twelve patents from Chiron-Viagene Inc. between 1995 and 2015



Other financial data show that the number of licenses of the patent of Introgene/Crucell is ten times higher compared to the average license percentage of the other 76 granted patents for gene therapies in 1995. The priority patent application EP 0833934 (with divisional and equivalent to US patent US6033908) was filed on June 15, 1995 and subsequently a patent portfolio of 48 nationally registered patents and ten US divisional patents was built. To generate revenues, the start-up company Introgene/Crucell decided to license their patented PER.C6® human cell line technology, after having received FDA approval for market authorisation, to third parties and major patent holders in the other life sciences and health domains (Merck and co., Rhône Poulenc, Millennium Pharma, Aventis Pasteur and GlaxoSmithKline) which eventually also led to the acceptance and dissemination of their technology. In this highly competitive field it was of key importance to appropriate this core technology⁵³ and to cooperate with third parties. This core technology was called PER.C6® and

⁵³ Anecdotal data from Crucell IP manager, 2014

contains a package of tools and know-how base, providing a safe and cost-effective manufacturing system for high-yield, large-scale production of vaccines and monoclonal antibodies. It is especially useful for vaccine manufacturing that requires the production of hard-to-grow viruses and holds the key to making such vaccines affordable for the whole world. As can be seen in **table 6.5**. Johnson & Johnson, who acquired Crucell in 2011, delivered more than 85 million doses of viral vaccines to UNICEF in 2014, to protect children in more than 60 countries against five serious infections (e.g. diphtheria, tetanus, pertussis, hepatitis B and Haemophilus influenza type B).

Table 6.5. Vaccines based upon Crucells' proprietary PER.C6 technology

Quinvaxem®	Fully liquid vaccine for protection against five major childhood infectious threats
Hepavax-Gene®	Recombinant hepatitis B vaccine
Hepavax-Gene ^{® TF}	
Epaxal®	Aluminum- free hepatitis A vaccine
Dukoral [®]	Oral vaccine against cholera

A direct relationship between the (market) value of a spin-off company in the biotechnology sector and the number of citations to their important (priority) patents can now be developed. Some researchers (e.g. Harhoff et al., 1999) describe the relationship between the numbers of all citations with the market value of companies as:

(6.1) ln (number of patent citations) = $0,314 \ln (\text{market value}) + 2$

In this case study, we used data from Crucells annual reports on their market capitalisation between 2001-2011, and plotted the natural logarithm of the total number of citations (defined as the sum of the number of patent citations to Crucells US6033908 patent in subsequent patent applications by third parties and self-citations by the company in their subsequent patent applications), against the stock value development of the company over time (= market capitalisation). An interesting correlation can be observed between the number of citations and the actual market capitalisation of the company. The accuracy of this correlation improves if we start at a value of 16 added to the number of citations (projected on the y-axis), apply a correction factor of 1.12 and use only the total number of citations by third parties. **Figure 6.4.** shows that between 2000-2010 the number of citations by third parties in a particular year (indicated by the blue coloured line) predicts the market capitalisation of the spin-off in following year (indicated by a red coloured line). In this figure both the number of annual citations (=CT) and the companies' annual market capitalisation are projected on y - axis.



2005

2006

2007

Figure 6.4. Time lag effect between the number of third party citations to Crucells

6.6. **Conclusions and discussion**

2001

2002

2003

(Ln CT + 16) * correction factor

2004

The data in this chapter show:

17.5 17 2000

> a. That the number of gene therapy patent applications increased spectacularly between 1985-2003, but decreased since;

2009

2010

2008

Ln Market capitalization in million €

- b. That statistical analyses of an IP landscape with a patent cluster of 93 gene therapies, similar to EP 0833934 filed in 1995, granted and registered in some 40 countries provide evidence that: a) US patent priority filing, b) the number of license agreements and c) the number of citations by third parties are significantly correlated to the length of their patent terms and hence its value for the patent owner;
- c. In the case of EP 0833934 of the Dutch biotechnology Introgene/Crucell, a close correlation can be observed between the number of citations by third parties to their priority patent application and the companies' market capitalisation in the following years.

The increasing importance of the commercialisation of academic patents in this sector, both in the USA and the EU, has become evident (Kers et al., 2014). Policy makers in the EU, Japan and the USA have realised that the so-called 'red biotechnology' in the sector of life sciences and health plays a crucial role in the development of the future public health. Both the recent revisions in the European Biotechnology Directive EG/98/44, followed by revisions on IPR ownership in the national patent acts and TT policies at universities play an important enabling role in this case. In some European countries special biotechnology clusters (or regions) received substantial support at national/regional level both in terms of financial assistance as well as in facility support (Zechendorf, 2011).

Based upon research on possible relationships between patent citations (both self-citations and third party citations) and company market value in various sectors of the economy, data often demonstrate skewed information. Where some researchers (Harhoff et al, 1999) relate the numbers of all citations with the market value of companies, the case of start-up company Crucell shows that only third party citations contribute to determine the market value. Although previous research showed that patent family size and opposition may be used as indicators to determine the value of patents (Harhoff et al., 2003) for patented gene therapies in 1995, neither size nor opposition could be positively correlated to the patent terms by universities and companies.

The successful commercialisation of the academic gene therapy patent by Dutch spin-off Introgene/Crucell is somewhat special, since at the time of the discovery and patenting of the invention of PER.C6 neither the Leiden University in The Netherlands, nor its' faculty of science had a formal IP policy in place or an TTO in operation. While the research was contracted by Introgene to the university and the inventors Frits Fallaux and Rob Hoeben were employed by the university, the other inventors, mentioned in the patent application (Bram Bout and Dinko Valerio) were employees of Introgene at the time. Between themselves, they decided that the priority patent was filed in 1995 in the names of both the university and Introgene and to be later re-assigned and transferred to Introgene in 1997. Nowadays, with established IP policies at university TTOs in place, the power of attorney and permission by the Board of Directors of the university is usually required for such assignment of patents, which could delay both participation in contract research and/ or the creation of a spin-off company based upon academic patents⁵⁴. And the claim 'although viral vectors may have become the vehicles for the gene therapist, more breakthrough inventions and technologies will be needed which will be based upon fundamental research' (Hoeben, 2001), suggests that further academic research will play an important role in future gene therapy developments.

Where the adaptation of innovations often goes hand in hand with their adoption by early adapters in their networks and systems of communication (Rogers, 2003), health innovations-related to the treatment of diseases and disorders are subject to clinical trials and market authorization procedures by the Food and Drug Administration⁵⁵ and the European Medicine Agency⁵⁶. Besides, the acceptance of gene therapies and biotechnology also depends on perceptions of citizens to avoid risk (Pardo and Calvo, 2006). Once a biotechnology company goes for an initial public offering (IPO) and becomes stock listed, it can distribute press releases to communicate to the general public that their prospected products have passed some critical phases of these trials, making investors aware that their products have come closer to market entrance (OECD, 2009).

The number of patented gene therapies increased until 2004 but the number of patents based on human genes is on the decline as off the year 1999. Their practice and use has been a topic of much (ethical) debate in society, which was aggravated by the death of eighteen year old Jesse

⁵⁴ Anecdotal data from ex- IPR manager, 2014

⁵⁵ FDA, fda.gov

⁵⁶ EMA, ema.europa.eu

Gelsinger at the university of Pennsylvania in 1999 (Nature, editorial, 1999). Since 2010, most gene patents contain synthetic sequences (Graff et al., 2013). Some 3,500 patents involving human genes will probably be invalidated in the USA after the decision of the US Supreme Court that isolated human genes are not patentable any longer (Nature Medicine, editorial, 2013). Our research data contrast those findings which claim that the percentage of biotechnology patents and pharma patents show levels under their top levels of application of 1996 (Lawrence, 2007). On the other hand, data on important biotechnology applicants in 2005 and 2006 (e.g. Genentech, Amgen, Chiron, Millennium Pharma, universities of California and Texas) correspond with the names of the companies and universities that have been identified in this study.

We conclude that the renewals of patented gene therapies are positively correlated with the number of licenses and the number of patent citations, and that therefore patent terms can be used as indicator to determine their value. In the case of the university spin-off Crucell, the number of citations by third parties to its priority patent application EP0833934 in a certain year is positively correlated to its market capitalisation in the following year. Here, we conclude that the number of citations can be used to determine and even predict the company's value.

Appendix A	International Patent Classification codes used to identify life sciences inventions			
A61B	Medical sciences, diagnostics			
A61B1	idem, instruments			
A61K	medical preparations			
A61K31	idem, using organic substances			
A61K35	idem, materials			
A61K38	idem, peptides			
A61K39	idem, antibodies			
A61K48	gene therapy			
A61K9	preparations with special form			
A61P	therapeutic effects of chemical compounds or medical preparations			
A61P25	idem, for the nervous system			
A61P3	idem, for the metabolism			
A61P35	idem, against tumours			
A61P9	idem, against cardio-vascular diseases			
С07Н	sugars with nucleic acid			
C07K	peptides			
C07K14	idem, having more than 20 amino acids			
C07K16	idem, immunoglobulins, e.g. monoclonal antibodies			
C12N	compositions of micro-organisms or enzymes			
C12N15	idem, genetically modified DNA or RNA, vectors, plasmids and their isolation or preparation			
C12N15/12	idem, recombinant DNA technology			
C12N5	idem, undifferentiated human, animal or plant cells e.g. Cell lines, tissues			
C12N5/10	idem, modified cells by the introduction of foreign genetic material			
C12N9	idem, pro enzymes			
C12Q	measuring processes			
C12Q1	idem, with enzymes or micro organisms			
C12Q1/68	idem, using nucleic acids			
G01	measuring			
G01N33/50	idem by analysis of the chemical/physical properties			
	using micro-organisms			
G01N33/53	idem, using biospecific assays			
G01N33/574	idem, bindings assays for cancer			
G01N33/68	idem, using peptides, proteins or amino acids			
G06F	electrical digital data processing			
G06K	recognition of data and data presenting			
G06T	imaging of data			

Appendix B

Global landscape of patent applicants in the Life sciences and Health sector, their country of origin and most important life sciences domains

Figure B.1. Major life sciences and health applicants (1995-2005)

Figure B.2.

Countries of origin of life sciences and health patent applications (1995-2005, %)



US= USA, DE= Germany, JP= Japan, GB= United Kingdom, FR= France, CA= Canada, CH= Switzerland, NL= The Netherlands SE= Sweden and KR= Korea

Table B.3Number and distribution of life sciences patent applications in three
domains filed between 1995 and 2005

	Domain:	Cancer	Immunology	Vaccines
Total numbers patent applications(*)		36, 375	17, 348	13,065
Distribu	tion of patent applications by I	PC (%)		
A61K	Medicines	33	33,1	33,9
A61K48	Gene therapy(**)	1,7	1,8	1,9
A61P	Therapeutic use	14,5	6,2	4,6
C07H	Sugars with nucleic acid	2,1	2,1	2,3
C07K	Peptides	7,0	13,2	15,3
C12N	Micro-organisms/enzymes	9,3	17,8	22,2
C12Q	Measurement	5,1	3,9	4,5
G01N	Chemical/physical analysis	8,7	6,6	5,9

IPC= International Patent Classification code

(*) A combination of PCT and EP patent applications

(**) Average percentage of gene therapy patents in the three domains = 1,8 %



Conclusions and discussion
7.1. Synopsis

In the last decades, science and innovation policies in both the USA and the EU contained instruments to stimulate research commercialisation. More recently, the commercialisation of scientific research also described as knowledge valorisation has become the 'third mission' of many European universities⁵⁷. Many game changing technologies (e.g. rDNA, PCR, RFID, Googles search engine) are based upon years of excellent scientific research followed by their introduction as innovations into the marketplace often after a decision either by university TTOs or individual scientists to patent corresponding research results (Wright, Lei and Merril, 2014). Scientists may be engaged in a multitude of pathways for research commercialisation, e.g. papers, material transfer agreements, collaborative research with companies, consultancy services, exchange of academic researchers for corporate R&D (Chai and Shih, 2013; Fini et al., 2010; Nelson, 2016; Sonmez, 2017), and this thesis focusses on 'patent-based research commercialisation'. Its objectives are to identify, quantify and analyse factors which can determine the contribution of academic patents to innovations thus creating socio-economic impact. Not only from a scientific point of view, but also from an innovation policy management and policy impact evaluation point of view (European Commission⁵⁸), it is important to examine which factors act as barriers or incentives for scientists to engage in patent-based research commercialisation.

Acknowledging identified knowledge gaps on how direct and indirect relationships between policy (innovation policy instruments), institutional (university IP legal regimes), organisational (university TT governance models) and individual factors (drivers which motivate scientists to use patents) may influence patent-based research commercialisation, this thesis describes how these factors can determine the yield, use and socio-economic impact of academic patents. Within the theoretical framework the general research question was: how do academic patents shape innovations and create socio-economic impact? This general, overarching question was then translated into five specific research questions: 1) How to identify academic patents and quantify their socio-economic impact? ; 2) Can we measure the impact of innovation policies to boost research commercialisation using patents?; 3) What are the relationships between the university IP regimes, their TTO governance models and their output in patents and spin-offs?; 4) What are the personal drivers of scientists that motivate them to engage with patent- based research commercialisation and 5) How to determine the value of academic patents and the value of university spin-offs that commercialise these patents?

Following sections in this chapter describe the main findings and conclusion of this thesis (section 7.2), and three specific conclusions about: a) the use of academic patents in relationship with science and innovation policies (section 7.3); b) scientists' motivations to engage in patents and relationships with employment effects (section 7.4); and c) university IP regimes and value of academic patents (section 7.5). Limitations which influence the

⁵⁷ First and second mission are: teaching and scientific research

⁵⁸ <u>https://ec.europa.eu/knowledge_transfer_2010-2012.pdf</u>

generalizability and representativeness of the findings plus suggestions for improvements in further research are discussed in **section 7.6**.

7.2. Main findings and conclusion

The analyses of longitudinal, empirical studies with quantitative and qualitative data extracted from some 3, 650 scientists across 148 universities in 30 European countries, who contributed as academic inventors and entrepreneurs to the commercialisation of some 5, 500 academic patents in a time period between 1995-2015, show:

- a. Significant, positive associations between *scientists' drivers to engage* in the commercialisation of their research, their use of patents and creation of spin-offs and between *university IP regimes*, scientists' research commercialisation and their use of patents;
- b. Evidence suggesting positive associations between *university TT governance* models and the yield of academic patents;
- c. No associations between an *innovation policy instrument* to boost research commercialisation stimulating the biotechnology sector and the increased number of academic biotechnology patents applications;
- d. An *employment effect* which can be associated with the commercialisation of academic patents by spin-offs; and
- e. Evidence suggesting that the *value of academic patents* can be measured in the same way as the value of patents in general.

In conclusion, the *individual motivation of scientists to engage with patent-based research commercialisation* is the main contributing factor inducing socio-economic impact of academic patents, followed by organisational factors (university governance TTO models) and institutional factors (university IP regimes). So, the kind of TTO governance model determines the yield of academic patents, a specific type of university IP regime determines the use of patents and the individual drivers of scientists determine the socio-economic impact of academic patents. And in line with the theoretical framework of this thesis, described in **chapter 1**:

(7.1) If I = Socio-economic impact $_{academic patents (AP)}$ in a country per year, then

(7.2) I = f (α.Scientists' driver * β.University IP regime * university TT governance model) * AP * Ap * Ut

where

parameter AP is the number of academic patents per country per year, which equals the number of universities in a country multiplied by the annual number of academic patents per university, parameter Ap represents the percentage of appropriated academic patents by companies (e.g. licensed, assigned or transferred) and parameter Ut is the utilisation percentage of this A (%) of academic patents by these companies. The scientists' driver in equation 7.2 refers to the factor describing the motivation of individual scientists to file patents in the course of the commercialisation of their research and the creation of a spin-off. The findings in thesis on the rank correlation coefficients (**chapters 4** and **5**) show that α is almost equal to γ and that both α and γ are $\gg \beta$. Depending on the percentages of parameters A_p and U_t , the socio-economic impact of academic patents in a country is largely determined by the university TT models and the drivers which motivate scientists to file patents for their research results in the course of research commercialisation. **Table 7.1**. shows a summarized, qualitative description of the contribution of studied sub- factors to the yield, use and socio-economic impact of academic patents is mostly determined by entrepreneurship-driven scientists using academic patents in spin-offs, having received adequate assistance at university TTOs, which are governed in a classical way.

 Table 7.1
 Factors determining the socio-economic impact, use and yield of academic patents

Factor	Effect					
	<u>Negative</u>	<u>Neutral</u>	Limited	<u>Considerable</u>	Large	
Drivers and			Recognition	Research	Entrepreneurship	
socio-						
economic						
impact of						
patents						
University			EU optional services type	EU full services type		
IP regime			Italian type	Swedish type		
and patent						
use						
University		Discipline-	Autonomous,		Classical, centralised	
TTO		integrated	decentralised			
governance						
and patent						
yield						

Figure 7.1. shows how three factors, described throughout this thesis, contribute significantly to the utilisation of academic patents in some of the phases of the 'Societal Impact Value Cycle' of knowledge valorisation (Van de Burgwal, Van der Waal and Claassen, 2018). It is possible to distinguish: a) engagement of 'entrepreneurial' scientists with patenting (especially in engineering and life sciences), b) the implementation of novel university IP regimes (university IP ownership vs. professors' privilege) and c) the implementation of (classical) TTO governance models (with obligatory contacts between scientists and TTOs). A dotted coloured line for a particular factor (e.g. university IP regimes, TTO governance models) means that this

factor contributed only to some of the phases in the stages going from unmet societal need (U) to feedback (F). On the contrary, scientists' engagement is required throughout all phases.

Figure 7.1. Factors determining the commercialisation of academic patents in the Societal Impact Value Cycle[©]



* Non- significant factor.

U= Unmet (societal) needs assessment, A= Articulating (policy) demands, S= Scoping science, R= conducting Research, O= Opportunity shaping, T= Transfer of technology, D_T and D_C = technical and commercial Development, P= Production, M= Market deployment and F= Feedback. (© Mark van der Waal)

7.3. The use of academic patents in relationship with innovation policies

Recently, many governments in the EU developed innovation policies to boost the commercialisation of scientific research. *Chapter 3* describes the impact of a Dutch innovation policy instrument (BioPartner programme) that provided funding for research in the life sciences research, reimbursement of costs of filing patents applications, thus enabling commercialisation of research results in the sector of biotechnology in the Netherlands. Although increased numbers of *academic* biotechnology patent applications were found, this policy did not contribute to a higher level of annually filed patent applications in the *biotechnology sector* (section 3.4.1). Based on additional, qualitative evidence, it can be concluded that the programme contributed to an increased level of IP awareness and behaviour amongst both university staff and scientists (section 3.4.3). Increased IP awareness of scientists in general, and available research instruments in future innovation policies in particular, may

contribute to a situation where more scientists engage in research commercialisation. Both quantitative and qualitative findings in this section contribute important insights to the body of literature, since they add novel, empirical evidence of the effects of innovation policy instruments for economic development.

One of the long-standing paradigms in academic patenting is the positive association between IP laws and the number of patent applications filed by universities. *Chapters 4 and 5* describe the impact of the implementation of these IP laws and regulations on academic patenting at 150 universities in 30 European countries. Analysing data from a European survey with patent data from scientists in all disciplines between 2010 and 2015, it became clear that they experienced an increasing pressure to engage in research commercialisation, which was primarily driven by (external) policies. Some 80% of scientists in all disciplines displayed proof of IP awareness, but only 34% was engaged with research commercialisation (16% of them with patenting and 7% with spin-offs, section 5.3.). University IP regimes, as a result of national IP laws and university policies, are positively associated with the numbers of academic patents, but not with spin-off creation. This section adds empirical evidence to the body of literature on academic patenting, spin-off creation and university case studies, at a European level.

Studies on patent decision management practices show positive correlations when using incentives to stimulate scientists to file patent applications. The dataset in *chapter 5* also provides insights into whether and how scientists filed patent applications in relationship with the driving forces that motivated them to engage in research commercialisation. The data showed that (especially) entrepreneurship-driven scientists in the engineering and life sciences are statistically significant more RC engaged, file more patent applications and create more spin-offs than scientists in other disciplines (Figures 5.4. till 5.7, in section 5.3.). The drivers which motivate scientists to file patents for the commercialisation of their research are far more important than university IP regimes.

Chapter 4 analysed university–industry technology transfer of patents in relationship with the governance of university technology transfer processes. The yield or output in numbers of patents and spin-offs of classically, centrally operating TTOs, which are incorporated into the university with offices located centrally on campus, are much higher than the outputs of other TTO governance models (section 4.4.). This section adds quantitative evidence of the impact of university TTO governance models to the body of literature. In conclusion it is clear that the choice to implement a specific university TTO governance model can have a significant impact on their output in academic patents and spin-offs. Higher, more intensive and more frequent, contact moments between scientists and TTO staff, might explain these significant differences in outputs. Since the choices to implement certain governance models of technology transfer processes are taken by university magistrates and TTO management, this chapter may also provide useful policy guidance.

Conclusion A:

Science and innovation policies may result in higher levels of scientists' engagement with, and output in academic patents and spin-offs, if these policies contain instruments for research funding, promotion of scientists' IP awareness, reimbursement of patent applications' costs and incentives to contact TTOs, but do not necessarily imply a significant higher number of total patents applications in a sector. Discussion

The conclusions on the growth in numbers of academic biotechnology patent applications in The Netherlands between 1990 and 2009 are in line with the growth observed in other counties in the EU (OECD, 2012; Lissoni, 2013). A spectacular increase of Dutch biotechnology patent applications occurred before the start of the BioPartner programme and the implementation of a national innovation policy to stimulate the life sciences sector. This early increase corresponds with global trends in biotechnology patenting rates (Barone, 2005). However, the percentage of university-owned biotechnology patents in the Netherlands is higher than that of other European universities (Lissoni et al., 2012) and the 47% of co-applications of academic biotechnology patent applications filed by Dutch companies and universities is considerably higher when compared to data from other researchers (Lissoni et al., 2009; Giuri et al., 2007). The 14% appropriation of academic biotechnology patent applications by companies and universities headquartered outside the Netherlands, is within common ranges of attrition of academic patents by multinational corporations (Arora, Belenzon and Patacconi, 2015) and demonstrates that the contribution of Dutch academic biotechnology patents to the globally operating biopharmaceutical sector is significant (Restaino and Tackeuchi, 2006). In this highly competitive sector industry-funded academic patented inventions are more likely to boost innovations (Wright et al., 2014; Fernald et al, 2014). In the early stages of the development of a biotechnology sector the contributions from the 'innovation ecosystem' in the Netherlands used to be relatively small and concentrated in three clusters (Leiden Bioscience Park, Utrecht and Amsterdam Science Park). The innovation policy instrument BioPartner enabled some 90 Dutch (spin-off) companies to appropriate some 340 biotechnology patent applications based upon scientific research at universities. By 2006, some 120 companies and technology institutes located in these three regional clusters were operational in the Dutch biotechnology sector (Enzing et al., 2004). These clusters are small compared to international clusters, such as the Greater Boston Area and San Diego in the USA, the Biotech Region Munich in Germany or the Paris biocluster in France (Van Geenhuizen, 2008). However, by 2014 some 590 dedicated biotechnology companies and institutes are operational in seven clusters in the Netherlands (Leiden Bioscience Park, Utrecht Science Park, Amsterdam Science Park, Health Valley, Rotterdam Science Tower, Groningen Business Generator and Brightlands Maastricht) and provide jobs for some 34, 000 FTE (Van der Giessen et al., 2014).

The conclusions referring to increased scientists' engagement with academic patenting in recent years are in line with previous research about universities in the USA, Japan and some Western European countries (Nagaka and Walsh, 2009; Giuri et al., 2007). Here, the finding that some 16% of European scientists in specific disciplines filed academic patents agrees with

data from other researchers (Audretsch and Göpteke- Hultén, 2015 and Lissoni, 2012). Contrary to their findings, but the data in this thesis suggest significantly higher levels of academic patenting by scientists at universities with a so-called 'EU full service' IP regime, especially for scientists working at senior university positions in the engineering and life sciences. Our conclusions that research- and entrepreneurship-driven scientists are above average engaged with patenting, are in line with national studies in Sweden and the UK (Hvide and Jones, 2016; Smith et al., 2010; Lam, 2010), but contrast data from research in Germany (Grimpe and Fier, 2010), which is probably due to the abolishment of the 'professors privilige' (Czarnitski et al., 2016). At some universities (e.g. in Italy and Ireland) higher rates of academic patenting can be attributed to university IP policies containing incentives to stimulate scientists to file patents as an important stimulus for their career (Fitzgerald and Cunningham, 2016). On a global level, patenting by European scientists is some 20% lower than for US scientists but higher than Japanese scientists (Nagaoka and Walsh, 2009). Time constraints and formal tasks, e.g. emphasis on education and research have been mentioned as prohibiting factors by scientists to refrain from research commercialisation in both the EU survey in this thesis as well as in prior research focussing more on IP-based start-ups (Åstebro et al, 2012).

The findings on the growing number of academic patents in the Netherlands are in agreement with prior research (Lissoni, 2012). Some studies on academic patenting in some European counties showed that the identification of university patents can underestimate the contribution of academic research to academic patenting by third parties (Lissoni et al., 2007; Tijssen et al., Tijssen 2002). The conclusions that the output of university TTOs in terms of produced numbers in patents and spin-offs is positively associated with the governance of technology transfer processes at TTOs are in line with earlier qualitative research at universities in the USA (Siegel et al., 2003). Although novel innovation policies and new IP acts have been implemented in the Netherlands and other European countries (Janssens, 2005), the increase in numbers of university patents in recent years has been far less spectacular than in the USA after the enactment of the Bayh-Dole legislation (e.g. KNAW, 2014; Lissoni, 2012; Geuna and Rossi, 2011; vs. Henderson, Jaffe and Traijtenberg, 1996; Mowery et al., 2001). The alignment between a national innovation policy and the introduction of governance models for university-industry technology transfer and IP strategy at TTOs has proven to be a lengthy process for the universities in the Netherlands and started fairly recently (2004).

7.4. Scientists' motivations to file patents in relationship with employment creation

Chapter 2 describes the results from an empirical, longitudinal analysis of academic patents, their commercial use by companies, and employment effects in various sectors of the economy in the Netherlands. Over a period of 10 years more than 1, 900 (from a stock of 2, 900) academic patent applications have been granted, appropriated and exploited by companies in the Netherlands (section 2.4.1). Depending on the size of companies, findings show that: a) multinationals tend to use academic patents to develop new markets and prevent others from applying for similar kind of patents, b) SMEs use patents to showcase their innovative capacity and develop new products, and c) spin-offs use patents mainly to acquire external funding for

product and market development. Data from a follow-up survey with university spin-offs⁵⁹ show that the exploitation of academic patents contributed to the creation some 9, 500 high-tech jobs in a time period of 10 years (section 2.4.2). So, it is concluded that the exploitation of academic patents has a positive contribution on employment creation. This chapter adds a novel methodology to the existing literature, enabling identification, quantification and exploitation of academic patents with follow-up tools to assess their contribution to economic growth and socio-economic value at company and national level.

Chapter 4 focusses on the implementation of the governance models of TT processes at universities and their impact on the output of academic patents and spin-offs. So far, the body of literature described these relationships only in qualitative terms, but this chapter adds quantitative data of some 2,660 European scientists, analysed at TTO level of some 150 universities in the EU. A much higher output in academic patents (yield) and IP-based spin-offs was found at universities with classically governed processes at centrally located TTOs than at universities- with autonomously governed, decentralised TTOs or at universities with discipline-integrated, regionalised TTOs (section 4.4). Increased levels of academic patents transfer towards regional SMEs occurred only at those Dutch universities that implemented a discipline-integrated governance model at regionalised TTOs (section 4.5). As a consequence, policy makers at university or regional level may decide to promote these autonomously governed technologies by SMEs and hence future regional economic development.

Chapter 5 describes the relationships between scientists' individual driving forces (e.g. recognition, research and entrepreneurship) which can motivate them to engage with research commercialisation. Entrepreneurial professors in the engineering and life sciences are more involved in patenting and spin-off creation than fellow scientists at other university positions or in other scientific disciplines (section 5.3). At European level, this chapter adds quantitative data showing that: a) *driving forces* that motivate individual scientists to commercialise their research, b) their *university position* and c) their *scientific discipline* are the most important factors determining their engagement with research commercialisation. University *IP regimes* are less important than scientists' *driving forces* (table 5.3 in section 5.3). Here, it is recommendable that policy makers at several levels design future policies giving entrepreneurial scientists more 'slack' and empower them as future 'change agents' thus enabling societal impact.

Conclusion B:

In the last decades, entrepreneurial scientists have become more engaged with patents that contributed to employment growth, if these patents were used as collateral for external funding and generated revenues during the process of spin-off development.

⁵⁹ IXA (2015), Utrecht Inc (2015), Yes!Delft (2015), Leiden BioSciencePark (2011), Kennispark Twente (2011)

Discussion

The interdependent effect of patents on job creation in small firms has neither been studied extensively (Arundel and Kabla, 1998; Levin et al., 1987) nor has it provided sufficient understanding of the processes by which scientists acquire entrepreneurial skills to make patents successful in the marketplace (Fryge and Wright, 2014). Efforts to identify such skills have been described in case studies in e.g. software industry (Chabchoub and Noisi, 2005) providing supporting data for the conclusions and the evidence of academic IP-based job creation in this thesis. The thesis conclusions on academic patenting by scientists are in line with earlier research stating that many academic inventors acquired their prolific IP behaviour prior to their academic career when working in the industry or private sector (Audretsch and Göpteke-Hultén, 2015: Lissoni, 2012). Contrary to common insights by policy makers in many European countries (OECD, 2013, 2003) the findings show that more than 30% of European scientists are engaged with commercialisation of their research. This percentage is comparable to the USA and Japan (Nagaoka and Walsh, 2009). The quantified level of academic patenting by 16% of European scientists agrees with prior research (Audretsch and Göpteke-Hultén, 2015). However, significantly higher levels of academic patenting by scientists are found at universities where patents, by national law, are assigned to the university and the use of TTO services is obligatory (so-called, 'EU full service' IP regime). The level of involvement with patenting by scientists in the USA and Japan is some 20% higher than by European scientists (Nagaoka and Walsh, 2009). The conclusions on the higher levels of academic patenting by professors in engineering and life sciences confirm conclusions from previous research (Lam, 2010, Van Looy et al., 2011). Here, the findings that research- and entrepreneurship-driven scientists are above average engaged with patenting, are supported by data in national studies in both the UK and Sweden (Lawton Smith et al. 2010; Hvide and Jones, 2016), but contrast data from earlier research about patenting scientists in Germany (Grimpe and Fier, 2010). The latter contradiction may be explained because in Germany the 'professors' privilege' was abandoned in 2002 (Czarnitszki et al., 2016). Data from Italian case studies on university-industry technology transfer are in line with the conclusions in this thesis, since they show the successes of centralised governance models for technology transfer with an IP strategy focusing on academic patent appropriation by firms (Rossi, 2010). In the Netherlands, the conclusions are supported by data on academic patenting- based scientific research between 2000 and 2009 (KNAW, 2014).

Surveying spin-off companies that appropriated academic patents in the Netherlands produced new evidence on associated impact on employment growth and financial value. Here, the conclusions on employment are partly in line with prior research showing that a positive association may not be induced by the ownership of the patent itself, but by exclusive patent inlicensing practices (Wright et al., 2014). The conclusions are partly contrasting prior research investigating the performance of university spin-offs vs. industry start-ups in Germany (Czarnitski et al., 2014) showing a 'performance premium' of 3.4% in employment growth for university spin-offs in all sectors of industry. This premium was correlated to a higher extent with the involvement of academic entrepreneurs in certain disciplines (e.g. law, social and natural sciences) than with the nature of the patented technology. The conclusions are in line with prior research in Denmark where academic patents contributed to an employment growth of (9.8-14.2)% more employees per company in two till three years after the date of a patent application (Chai and Shih, 2013). The selection of investigated companies has been based upon their increase in the number of filed patent applications by 520% and granted patents by 430%. The conclusions are complementary to those showing that low levels of resources (e.g. human, financial) and the possibility to patent the core technology had a positive impact on growth during the growth path of young technology- based companies in Belgium (Clarysse, et al., 2011). The conclusions on patent-based employment confirm findings in a large-scale study in the USA, showing that the granting of some 48, 000 US patent applications was positively associated with the creation of jobs, growing of sales and the chance to be acquired by external investors (Farre- Mensa et al., 2015). Unexpectedly, the findings are complemented by recent research in the USA showing that the role of patents is strongest for start-ups founded by inexperienced entrepreneurs with a 55% higher employment growth rate and for firms in information technology sector (Farre- Mensa et al., 2017).

Contrary to the findings in the case studies on business exploitation of academic patents in the Netherlands showing that multinational firms (section 2.4 and 3.4) have been the largest absorbers of academic patents, data from longitudinal studies in Sweden on academic patent filings, transfer and commercialisation showed that in this case SMEs were the largest absorbers of academic patents (Dhalberg et al., 2017). The conclusions on company growth are not confirmed by in Belgian data from 20 years of longitudinal research on company patents with and without academic inventors. In this study, the companies examined collaborate with universities in development trajectories of novel, more risky and non-core business technologies, which did not contribute to (faster) company growth (Peeters et al., 2015). The findings indicating that scientists experienced the university TTO support as insufficient (e.g. network, new business development) are confirmed by recently conducted research (Gümüsay, and Bohné, 2018).

Nevertheless, considering that scientists in general seem to be evaluated on the basis of their educational and research output during their annual job reviews (Åstebro et al., 2012) and not on their contribution to research commercialisation, there is room for policy adaptation.

7.5. University IP regimes and the value of academic patents exploited by spin-offs

Using a bottom-up approach to collect data and survey European scientists at individual level, *chapter 5* describes how scientists have been engaged in patenting and spin-offs between 2010 and 2015. This chapter adds to the body of literature a novel typology of university IP regimes (which are described as 'EU full services type', 'EU optional services type', 'Italian' or 'Swedish types') presenting the full spectrum of IP ownership and TTO regulations in Europe. Statistically-significant differences in the output in numbers of academic patents (yield) and IP-based spin-offs can be associated with both institutionalised IP regimes at their universities and the driving factors that motivate scientists to engage in research commercialisation (section

5.3). Scientists' motivations to engage in patenting and spin-offs are much more important than the IP regimes of their universities.

Four university case studies (National University Galway in Ireland, Aalto University in Finland, Politecnico de Milano in Italy and Karolinska Institutet in Sweden) describe all possible relationships between scientists' engagement with research commercialisation within examined university IP regimes types (resp. EU full service, EU optional service, 'Italian' resp. 'Swedish' type). This shows empirical evidence that more scientists are engaged with academic patenting and contact their TTO when obligatory research commercialisation services are provided by university TTOs (table 5.5. in section 5.3). On the other hand, Swedish scientists, who still enjoy the 'professors' privilege', are more involved with the creation of spin-offs than their peers who work at universities with 'Italian' or 'EU optional service type' IP regimes.

In contrast to significant, positive associations between *scientists' motivations* and the *number* of university spin-offs, no positive associations in the relationship between university IP regimes and spin-off development were found. Therefore, it is concluded that the individual driving forces of scientists, which motivate them to file patents and use them in a spin-off, plus a systematic support for academic patenting at a university TTO, are the key success factors that determine how academic patents in pathways of research commercialisation create socio-economic impact. These factors also have an impact on e.g. patent designations to other countries after the grant of the patent application, development of prototypes, and further exploitation by start-ups or spin-offs, in-licensing of academic patents by existing companies, out-licensing and income generation. Future *science and innovation policies* might enhance the research commercialisation outcome, if *their design aligns with the motivations* from those scientists, who aspire to start a new venture, using academic patents.

The survey data in *chapter 2* with IP- based spin-offs in the Netherlands show that academic entrepreneurs earned approximately \notin 40 000 in business related to the commercialisation of their academic patents during the first five years. Some 'blockbuster' revenues (\notin 1 000 000 or more) have been found in all company categories (section 2.4.2). Two international case studies in *chapter 6* indicate that the value of academic patents for gene therapies can be determined by their patent terms and the numbers of licenses (section 6.4). The financial value calculations of an academic patent, exploited by Dutch university spin-off Crucell over a time period of 10 years, showed that the number of third-party citations to their patent in any particular year can be used as an indicator of the market capitalisation of this company in the following year (section 6.5). This time lag effect of patent citations in relationship to a company's market capitalisation is a new observation and a finding which may have important commercial implications.

Conclusion C:

The yield, successful exploitation and value creation of academic patents by spin-offs can be: a) correlated with the number of citations by third parties, and b) associated to a higher degree with the motivations of (entrepreneurial) scientists and the university TT governance model than with the IP regimes of their universities.

Discussion

In the last ten years, university IP regimes and practices of TTOs at universities in Europe have become more in compliance with the recommended 18 Codes of Practices of the EU (Arundel, 2013). The conclusions are in line with data from a longitudinal study of some 1,200 spin-offs from 66 universities in Italy, showing that the rate of establishment of technology spin-offs increases when more entrepreneurs are appointed as laymen at TTOs and/or boards of directors. Involvement of local stakeholders in the university's board of directors can be associated with increased establishments of service-oriented spin-offs (Meoli et al., 2017). The number of university patents at Irish universities was found to be positively correlated with the 'mission statement' of the university, enabling technology transfer and entrepreneurship in the region (Fitzgerald and Cunningham, 2015), which is in line with the conclusions in this thesis. The conclusions also agree with research in Sweden, where universities have the 'professors' privilege'. Given the population of some 10 million inhabitants and the presence of ten multinational firms, Swedish policy makers strongly advocate the importance of successful spin-offs and start-ups (Åstebro et al., 2012). In the case of Norway, a survey among inventors working at public research organisations studied their motivations, university support structure and development of academic patents. Contrary to the conclusions in this thesis, university TTO support and the incentives for Norwegian scientists seemed to matter little (Gullbrandsen et al., 2008).

The conclusions on the effects of an autonomous, decentralised governance model for technology transfer contrast data from results from 16 European case studies (Schoen et al., 2014) that, unlike the research described in this thesis, were based upon interviews with TTO staff and data from websites' of TTOs and universities. The conclusions on the research commercialisation effects of TTOs governance models are in line with previous research that was based upon a survey at eleven European university TTOs showing that increased patent transfer to spin-offs occurs at universities with an autonomous, decentralised governance model for technology transfer, provided that the right incentives are available for entrepreneurial scientists (Debackere and Veugelers, 2006). Previous research emphasises the importance of such incentives (e.g. finance, time, IP ownership, consultancy, matchmaking services) for both scientists and university TTOs at other European and universities in the USA (Muscio, 2010; Friedman and Silberman, 2003). However, in this thesis no data were found confirming that university-industry technology transfer towards SMEs strongly depends on personal contacts between scientists and entrepreneurs (Freitas et al., 2013).

Our findings on academic patent values are partly in line with results from the Europe-wide PatVal-EU study (Giuiri et al. 2007; p. 1121) and partly with data on the value of academic patents in Denmark, France, Italy, the Netherlands and Sweden (Lisssoni and Montobbio, 2015). These scientists showed that academic patents in the Netherlands are more cited than non-academic patents, irrespective of their ownership, while university-owned patents in Denmark and Italy get fewer citations than non-university owned patents. The findings about the creation of academic patent value agree with findings from a large survey on some 2,000 academic scientists in the USA, showing that the likelihood for licensing depends strongly on research collaboration with researchers in industry (Wu et al., 2014).

7.6. Limitations and suggestions for further research

Following the conceptual and analytical framework in this thesis, patent case studies, surveys and interviews were designed and acquired data were analysed to answer the research questions. Empirical studies face challenges in terms of available resources, data and time. The way case studies and surveys are designed influences statistical representativeness and generalizability of research findings presented in chapters 2 till 6. This last section will discuss the limitations of this research in general and provide suggestions for methodological improvements and ideas for future research.

Data limitations

Identification and utilisation of academic patents is problematic as a central or national register with address information on inventors in patent applications within patent databases is often missing.

Considering the duration of the granting procedures for patent applications and all distinctions between patent applications (USA: patent pending), granted patent applications (asserted rights) and validated patents registered in national jurisdictions, the priority filings of academic patent applications, based upon research at scientific research at universities, have been measured as unit of research throughout this thesis. In such patent applications, tenured academic staff is mentioned as inventor by definition.

In the case study of business sector exploitation of academic patents in the Netherlands, I used a small sample size of 230 surveyed academic patents (section 2.4). Although the overall response rate was acceptable, the response on particular survey-items was biased, such as the response by spin-offs which was much higher than those of SMEs and multinationals. For instance, the employment creation effect of academic patents was only available for university spin-offs for 10 years. The effect parameter of this socio-economic impact of academic patents could potentially be much larger if the observation period would have been longer than 10 years. This hypothesis could be validated if the cross-sectional survey approach of this study will be replaced by a longitudinal- large scale survey involving not only spin-offs, but also SMEs and multinationals. Since the mid 1980s many thousands of life sciences and health and gene therapy patent applications have been filed globally. The sampled 93 gene therapies are classified in the same patent classification codes as the invention of spin-off Introgene, and were sampled for an IP landscape to analyse their fate. Though the landscape study yielded interesting data, it cannot claim representativeness or completeness (section 6.4). The *limited dataset* from this case study suggest that the value of academic patents can be measured in a similar way as the value of patents in general, e.g. patent terms, number of licensees and patent citations. Despite the small sample, this case study resulted in first-of-a-kind data about the relationships between the patent terms and citations of academic biotechnology patents on the one hand side and the exploitation of academic patents by (spin-off) companies on the other hand side. Future studies could employ the methodology used in this case study and apply it to a much larger sample of academic patents to validate findings and increase representativeness (e.g. valid gene therapy, biotechnology patents).

Methodological limitations

The utilisation of academic patents creating socio-economic impact in the market place can be studied in several ways. It is possible to quantify the number of academic patents in an economic sector. To study the impact of an innovation policy for the biotech sector in the Netherlands, I developed and carried out a case study to quantify academic biotechnology applications which have been reimbursed by financial instruments provided by a Dutch innovation policy. To quantify innovations and job creation, and to measure the socio-economic impact, utilisation and valuation of granted academic patents, I developed and conducted country specific webmail surveys in particular countries, or technology specific IP landscapes (e.g. gene therapies, life sciences). To study IP engagement of scientists a survey a European study was conducted to collect data about scientists' patent awareness and use. Here, I studied the relationships between university IP regimes, university TT governance models and the drivers that motivate scientists to file patent applications.

Where engineers use patents as a source of technical information to solve problems during R&D projects (Sandal and Anand, 2016), social scientists and economists can analyse the socio-economic impact of academic patents to showcase the complex nature of collaborations between academia and the business sector over a longer period of time (Sternitzski et al., 2008) or use patents as indicator for technical developments at global level (Leydesdorff et al., 2014). Given the lengthy, high risk and uncertain outcome of innovation projects, future research on the impact of innovation policies in relationship with the utilisation of academic patents will benefit if not only the short-term but also the *long term socio-economic impact* will be studied. In doing so, data about the potential effects which occur after the closure of policy-implemented programmes will then also be accounted for (sections 2.4, 3.4.2 and 4.5).

Representativeness

The statistical representativeness of respondents and data in the surveys among European scientists has limitations (**chapters 4** and **5**). The sample size exceeds minimal requirements for statistical analyses and the stock of available 79, 200 individual data (e.g. university, faculty, discipline, position, age, gender, TTO contact, TTO support, patent filed, spin-off involvement) extracted from some 2, 650 European scientists is large. But the response rate from European scientists in this survey was less than 10%.

Considering the responses of scientists classified in their four university IP regimes (EU full service, EU optional service, Italian and Swedish), I then measured if the control variables (age, gender, disciplines and university positions) of responding scientist are comparable to those of non-respondents. Considering that per university IP regime, the percentages in control variables for non-respondents do not differ much from those of the responding European scientists, the level of statistical representativeness of findings in **chapter 5** do pertain not only to populations of scientists in Sweden (Swedish IP regime type), Italy (Italian IP regime type), Finland (EU 'optional' IP regime type) and the Netherlands (EU 'full service' IP regime type) but also to scientists working with similar university IP regimes in other European countries.

In a country case study on relationships between university TT governance models and the transfer of academic patents in the Netherlands (**chapter 4**), the issue of representativeness is critical due to the large non- response rate. Here, any findings or even conclusions are under debate and can only be validated by future research once we have collected more, reliable data.

Suggestions for further research

Improved administration records by university TTOs, made accessible through a public register of academic inventors of the kind now partially developed within the APE-INV project would be welcomed (Lissoni, 2013). Matching methodologies with disambiguation procedures to identify positive relationships between authors–inventors will help to correctly identify the majority of academic patents (Maraut and Martinez, 2014). More recently, the combination of commonly-known online services with robust processing power and artificial intelligence can provide interesting options. Nowadays, Google Patent covers multiple, different international patent office databases, but does not index patent citations or allow automatic searches. A semi-automatic indirect method via Bing has been used to extract and filter patent citations from Google to academic papers in Scopus with an overall precision of 98% (Kousha and Thelwall, 2015). Complicated methodologies to produce citation patterns of both academic papers and patent documents can make them sometimes hard to apply (Mihara, 2012). For globally- active applicants, a partial solution for this problem may be to use patent data from the largest patent offices (e.g. USA, Japan, India, Europe, China), sample data and combine them with the patent family information (Namakura et al., 2015).

Considering the global importance of research commercialisation to address societal needs, future research about the impact of university IP regimes and scientists' drivers for patenting and spin-offs (section 5.4), should be extended towards universities in other continents (e.g. Australia, Brazil, China, India, Russia and South Korea). Further studies will greatly benefit from standardisation of formats for data collection, including data about financial resources for spin-off development and funding for scientific research.

Patent-based data are frequently used as indicators in empirical research to measure innovation and technological change. Notwithstanding proven evidence in some particular cases of life sciences patents citing to publicly-funded, there is still limited evidence on how patent-based indicators relate to product/process/market innovations. Further research is recommended to study whether it is possible to link the outcomes from product development and commercialisation, which capture either invention's value or the uncertainty surrounding the patenting process, to the outcomes of the product development processes, with detailed patent data. While patenting tended to increase the speed of- and added value from commercialisation on the one hand, they reduced uncertainty on the other hand (Wagner and Wakeman, 2016). In this thesis the utilisation of academic patents was mainly focussed towards the biotechnology and life sciences and health sectors (sections 3.4.3 and 6.2), and future research into the effects of innovation policies should study how academic patents have utilised by companies into innovations in other sectors. In such kind of research patent designations, payments of annual patent renewal taxes (Dechezleprêtre et al., 2017) and patent licenses to and patent citations by third parties (Hall et al., 2007) can be used as indicators for innovation (see e.g. section 6.3).

At *institutional level*, the effects of the development and implementation of a university IP policy determining the contractual obligations of scientists to contact a TTO for patenting and patenting by scientists as stimulus for their career should be studied.

At *organisational level* studies on the relationships between the utilisation of academic patents and the mission of a university, patent use restrictions due to contractual obligations in public private partnerships and/or the growing development of academic entrepreneurship in university ecosystems, are recommended.

At the *individual level* of scientists it is important to examine whether in the course of research commercialisation, either scientists' IP awareness or the obligation to contact a university TTO is key in the decision making process to file a patent application. Regarding the small, national dataset (**chapter 2**), another topic for further investigation would be to examine if the exploitation of academic patents by entrepreneurial scientists, using their patented invention in an independent spin-off is more successful (Stam, 2013), than their exploitation by SMEs and multinational companies.

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Glossary

Academic entrepreneur	an entrepreneur that is or has been working at a university and is involved with the commercial exploitation of a patent in a spin- off
Academic patent	a granted patent based upon university research results in which at least one of the inventors has a university position at the date of the filing of the patent application.
Academic inventor	a scientist with a contract at a Public Research Organisation (e.g. university) whose name is mentioned as inventor in a patent application
Biotechnology	a technology that uses living systems and/or organisms to develop or manufacture useful products
Collaborative research	research conducted at a university for a public private partnership
Contract research	research conducted at a university financed by a private company
Discoveries	scientific experiments that led to new insights and knowledge
Drivers	scientists' motivations to engage into the commercialisation of the research results
Economic growth	growing GDP per capita in a number of years
EP patent	patent application filed via the EPO
EPO	European Patent Organisation, responsible for the search and examination of EP patent applications of contracted member states
Epoque	a patent database used by patent examiners of the EPO to define the State of the Art in the process of the granting of a patent application
Espacenet	an open access patent database that contains more than 100 million patent documents
Exploitation of an academic patent	the commercial use of a patented product or process based upon scientific research

Genomics	scientific discipline that applies e.g. recombinant DNA, DNA sequences, bio information to sequence, assemble and analyse the function and structure of the genome
Innovation policy	policy of a national government or regional organisation to encourage persons, companies and universities to and provide them with tools and resources to bring more innovations to the marketplace
Innovation	successful introduction of a product or process in the marketplace
Intellectual Property Rights (IPRs)	appropriated ownership rights, e.g. patents, trademarks, designs, copyrights, plant breeders rights, databases to monopolise markets temporarily as determined by international treaties, national laws, regulations and (employers) contracts or agreements
Invention	a technical solution for a problem
Invention disclosure form	a form which describes the research results in such a way that they may contain an, economically interesting, invention which may need patent protection and IP ownership
Knowledge valorisation	commercialisation and contribution of scientific research results to (technological) innovations in society
LSH sector	life sciences and health sector (e.g. public health, aging population, food security) providing niche- market for biotechnology innovations
National IP framework	national laws and regulations to promote technology transfer between universities and companies (e.g. competition law, contractual law, education act, regulations on services for third parties, intellectual property laws)
Patent	a granted and registered exclusive right that gives the patent owner a national monopoly for twenty years to stop a third party from the commercial exploitation of the patented invention
Patent application	an official procedure to apply for a patent at a national or international patent granting agency in order to appropriate an invention in a country

Patent citation	citations to patent documents in international search reports by patent examiners of patent granting agencies in the process of the granting and validation procedures
Patent family	after filing a patent application for one invention the patentee can designate multiple countries to enforce the exclusive rights for the commercial exploitation of the appropriated invention
PatStat	The official name of this database is EPO Worldwide Patent Statistical Database (PATSTAT)
Public Private Partnership	a temporary consortium of universities, technology institutes and companies, e.g. involved in scientific research in order to solve a number of (technical) problems within a certain sector of economy or part of society
Public Research Organisation	a public university, knowledge or technical institute involved in scientific research and financed by a ministry, research council or organisations primarily responsible for financing scientific research
Priority patent application	First patent application for one invention worldwide
Research commercialisation	modes and pathways to exploit scientific knowledge (e.g. contract research with industrial partners, consultancy, spin-off or in a start-up company) with or without a patented invention
Spin-off	a company created by university scientists based upon an academic patent
Start-up	a company founded by university alumni or (PhD) students
Technological innovations	new ideas, devices or methods that meet new requirements or existing market needs through the provision of more-effective products, processes, technologies or business methods and enabled by engineering processes that solves a problem in a technical or scientific way
Technology Transfer	a process at a university with a range of services to enable research commercialisation from a university to the public and private sector and the use of a appropriated invention by a third party

Technology Transfer Office	an office at or outside a university (often placed under the responsibility of the Board of Directors or Deans) with the tasks to acquire funding for scientific research, enable contract research, file patent applications, arrange patent licenses with companies and facilitate creation of spin-offs
Theory of economic growth	the use of technological, social and managerial innovations that can stimulate growth and productivity in a sector or company and thereby create new jobs
Unique invention	refers to the first (priority) patent application of an original invention that may have been registered in many countries
University IP management	Arrangements on ownership, licensing and management of patented results from scientific research usually facilitated by the TTO (e.g. invention disclosures, filing a patent application, incentives for personnel, creation of spin-off)
University IP regimes	university research commercialisation or valorisation policy that is determined by national IP laws and regulations governed by a university and usually implemented by a TTO (e.g. collaborative or contract research, patent applications, licenses)
University-held patent	a patent application filed and owned by a university
University-invented patent	a patent application by a university or a third party based upon scientific research at a particular university
University valorisation policy	policy of a university to enable socio-economic impact of scientific research in different modes and pathways
Utilisation of an academic patent	the effective use of an academic patent usually after a transfer, license or assignment to a company followed by a market introduction of the patented innovation
Valorisation	A translation process from scientific knowledge into valuable products and processes to address societal needs
WIPO	The organisation of the United Nations responsible for the Global harmonisation of intellectual property rights

Summary

The importance of innovations for companies has been described in the 1920's by Schumpeter in his ground breaking theory on 'creative destruction'. The use and appropriation of patents and other Intellectual Property Rights (IPRs) by companies, which allow them to capture market positions, gain profitable margins and returns on investment have been studied and are as such a part in the body of the economic literature (Teece, 1993). More recently, the fact that excessive exploitation of IPRs can result into negative, too exclusive effects, marginalisation and sometimes to uneven prosperity distribution within and between countries has become under dispute (Stiglitz and Henry, 2006). Especially with regards to the prices of innovative medicines, some policymakers regard patents as instruments that grant 'big pharma' too strong monopolies.

Science and innovation policies formulated within the 'triangle' shaped by national governments, companies and universities can stimulate the innovative power and hence the prosperity in a society. At a global level, universities have become important engines for innovations and since the 1980-s the formal tasks of universities⁶⁰ in most European countries now also entail 'research commercialisation' (RC). In the USA, research from Mazzucato (2014) demonstrated that publically financed research contributes to almost all recent innovations, e.g. medicines, iPhone. Due to business-economic and financial reasons, many multinational companies restructured their Research & Development departments and opted for more public-private-partnerships with universities in a so-called open innovation system, in which access to and ownership of IPRs are of key importance. The various types of quantifiable RC output include contract research, collaboration with industrial partners, consultancy, creation of spin-offs and filing of patents. However, the institutionalisation of RC activities via university Technology Transfer Offices (TTOs) is of more recent date and empirical evidence on links between patent-based RC and its socio-economic impacts is scarce (organisational factor). The intricate relationships between the engagement of scientists with the commercialisation of their research and university IP regimes, on the one hand, and the socioeconomic impact of academic patents in relationship with TTO governance models, on the other hand, are not clear and merit more extensive, empirical and longitudinal research.

Although the impact of national IP laws and regulations in Europe on academic patenting (*institutional factor*) has been studied extensively, there is still a scarcity of data explaining why scientists engage with RC. Studies on scientists' drivers (*individual factors*) to engage with RC cover fragmented topics: impact creation in e.g. the biotechnology sector; importance of patents for academic careers and non-financial incentives to involve scientists into invention disclosures. Studies in the USA show that drivers for scientists to engage with RC related to access to extra funding, or legal obligations. The effectiveness of policies stimulating RC (*policy factor*) also depends on the effectiveness of university-industry technology transfer including IPRs; characteristics of innovation systems and IP awareness of scientists, but data about the impact of policies to stimulate RC, technology transfer (TT) and the use of academic

⁶⁰ Education and research
patents are limited. Acknowledging above described knowledge gaps, the general overarching research question of this thesis is:

"How do academic patents shape innovations and what factors effectively determine their use in pathways of research commercialisation"

Hence, this thesis addresses three interrelated issues: (a) why scientists engage with academic patenting; (b) influence of TTO governance on the use of academic patents; (c) impacts of innovation policies aiming to boost patent based RC in Europe. This thesis presents a theoretical framework and empirical data from patent-based studies, surveys, questionnaires and semi-structured interviews. All chapters in this thesis have been based on articles addressing scientific research on the relationships between institutional (policy, legal, financial), organisational (support from university board and TTO, RC services) and individual factors (motivation, time, experience) and the use of patents and IP-based spin-offs at universities in Europe. In order to generate more scientific insight and bridge abovementioned gaps, eleven sub-projects have been conducted between 2012 and 2017 to examine these relationships (see **table 1.1.**). Although some indicators (e.g. patents and spin-offs) tend to be primarily aligned with scientists at the faculties of science and engineering, our research also involved scientists from other disciplines (e.g. economics, social sciences).

The commercialisation of academic patents has been studied longitudinally in relationship with their utilisation in a business sector (**chapters 2 and 6**). The thesis describes how:

- Some 66 % of Dutch academic patents has been appropriated by companies between 2000 and 2010;
- The exploitation of academic patents by IP-based university spin-offs may create jobs on the condition that the entrepreneurial scientist have used the patent successfully for funding;
- The value of academic gene therapy patents was significantly and positively correlated with the number of patent licensees and number of third party citations;
- The average revenue per Dutch academic patent amounts to some € 42 000

Although our research on the impact of innovation policies stimulating RC through the use and exploitation of academic patents in the biotechnology sector shows that the latter is still a topic for further research (**chapter 3**), we found that during the life time of a policy instrument enabling academic patenting (BioPartner program in the Netherlands):

- IP awareness amongst scientists has increased;
- The number of academic biotechnology patent applications increased;

Using a novel typology of university IP regimes and existing university TT governance models, patent-based RC data of European scientists were acquired and analysed (**chapters 4 and 5**). In addition to the body of literature, here the findings show that:

- Psychosocial factors that motivate individual scientists (e.g. entrepreneurship-driven) to use patents are much more associated with their RC than the institutional and organisational factors for technology transfer (IP regimes);
- The creation of IP-based spin-offs is only associated with these individual factors and not with the institutional and organisational factors for technology transfer;
- The IP output of TTOs can be associated with obligatory contact between scientists and a centrally located university TTO;
- The transfer of academic patents by university TTOs can be associated with their governance models

Analysing longitudinal, empirical data extracted from some 3,650 scientists across 150 universities in 30 European countries who produced some 5,500 academic patents in the years 1995-2015, this thesis *concludes* that:

- (a) Science and innovation policies may result into higher levels of scientists' engagement with- and output in academic patents and spin-offs, if these policies contain instruments for research funding, promotion of scientists' IP awareness, reimbursement of patent applications' costs and incentives to contact;
- (b) In last decades, the category of entrepreneurial scientists in particular has become more engaged with patents that contributed to employment growth if these have been used as collateral for external funding and revenues during the process of spin-off development;
- (c) Successful exploitation and value creation- of academic patents by spin-offs can be: 1) correlated with the number of citations by third parties, and 2) associated to a higher degree with the motivations of (entrepreneurial) scientists than with the IP regimes of their universities.

Although the majority of academic patents may be commercialised by SMEs and multinationals and not by university spin-offs, this thesis has shown that individual factors, which drive scientists to file patents and create IP-based spin-offs during the course of the commercialisation of their research, are (much) more important than organisational and institutional factors. The utilisation of academic patents by (academic) entrepreneurs in these spin-offs eventually creates societal impact like novel innovations and jobs.

Dankwoord

De uitvoering van onderhavig promotieonderzoek op gevorderde leeftijd kent vele voordelen. Bij dit multi- en interdisciplinair wetenschappelijk onderzoek is niet alleen voortschrijdend inzicht van belang gebleken maar tevens de mogelijkheid om naar eigen inzicht en behoefte tijd te alloceren, om samen te werken en teamwork te verrichten. Deze dissertatie is het resultaat van onderzoek dat ik als buitenpromovendus aan de faculteit der Bètawetenschappen aan de Vrije Universiteit in afgelopen jaren heb mogen uitvoeren. Dankzij de medewerking van vele wetenschappers, academische uitvinders, ondernemers, medewerkers van kennisinstellingen, kennistransferorganisaties en bedrijven heb ik data kunnen verzamelen en analyseren over factoren, die van invloed kunnen zijn op de maatschappelijke impact van geoctrooieerde resultaten van wetenschappelijk onderzoek.

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Collega-promovendi aan het Athena Instituut van de Bètafaculteit aan de VU, dr. Bahar Ramezanpour, dr. Kenneth Fernald, dr. Esther Pronker, Linda van de Burgwal en Mark van der Waal, dank voor onze discussies en feedback. Anne Neevel, extra dank voor de samenwerking tijdens het Business Management onderwijs aan de faculteit.

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Dank aan die KTO medewerkers van 10 Nederlandse universiteiten die hebben bijgedragen aan de validatie van Nederlandse academische octrooien tijdens de zgn. Regionale Innovatie Systemen (RIS) studie waarnaar wordt verwezen in hoofdstuk 2. Dank, drs. Erik van der Linde en ir. Arie Korbijn, om de resultaten van de RIS te gebruiken bij het op stellen van het KNAW rapport 'Benutting van octrooien op resultaten van wetenschappelijk onderzoek' (2014). Dank, prof.dr. Clemens van Blitterswijk en dr. Kees Eijkel voor de presentatie van de octrooidata uit dit KNAW rapport, en jullie suggesties voor vervolgonderzoek naar de relaties met academisch ondernemerschap.

Subsets uit eerdergenoemde RIS studie zijn tussen 2013 en 2016 geanalyseerd en gebruikt in de hoofdstukken 3 en 4. Dank, Roline Brunnekreeft, Zainab- Noor el Hejazi en Valesca van Zwieten voor jullie 'semi-structured' interviews waarvan bepaalde data zijn verwerkt in hoofdstukken 5 en 6.

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About the author

After secondary school at the Groen van Prinsterer College (VWO) in The Hague, Peter van Dongen studied at Wageningen University and Research Centre. He obtained an engineering degree in physico-chemistry processes in soil and water environments in 1986, plus a masters' degree in innovation and communication studies in 1987.

He was assigned as associate-expert at the Food and Agricultural Organisation of the United Nations (Rome, Italy), and worked for 5 years in soil- and water projects in Ethiopia and Bolivia. On return in the Netherlands, he started to work as freelance consultant, later as project engineer at Wageningen-Delft university spin-off SAWA, that later merged into the Arcadis engineering company. During those years he was responsible for (Research and Development) projects on the use of organic fertilizers, water supply and sewerage in countries in Europe and Africa.

As EMEA manager at a Canadian university spin-off developing into Trojan Technologies Inc., he was holding responsibilities for research and marketing on ultraviolet water disinfection reactors for ultrapure, potable and waste water applications. During those years, he learned to practice and appreciate the exploitation of the IPR portfolio for business, product and market development. He acquired hands-on experience with IPR based business management in open-innovation systems, working with suppliers (e.g. Philips, Nedap, General Electric, Allen Bradley and Siemens) and in public private partnerships with professors and PhD students at several technical universities in western European countries.

In 2001, he was appointed account manager and IP advisor for universities at the Netherlands Patent Office (a division of the Netherlands Entreprise Agency). As a secretary of the National Platform on University Patent Policy- a supervisory body consisting of the AWTI, funding agencies for scientific research (KNAW, NWO, TTW), board members of the Dutch four technical universities and the IP managers of Dutch multinationals- where he was instrumental during the draft of a framework of university IP policy recommendations for the Ministries of Economic Affairs and Education, Culture and Science. These recommendations have been implemented in then forthcoming innovation policies, supporting research commercialisation and knowledge valorisation (e.g. Technopartner and Valorisation Programme).

Currently, he is an external member of the Dutch expert group on Knowledge and Technology Transfer, secretary to the Advisory Board of IP teaching and member of the Licensing Executive Society (LES) Benelux. Since 2010, he frequently lectures at various faculties of Dutch universities on IP strategies for value creation and capitalisation, the use of patent databases and IP licenses. During his work at the Patent Office, he developed a keen interest in IP-based spin-offs, academic entrepreneurship in the sectors of biotechnology, life sciences and sustainable engineering.

Personal hobbies are sports, literature, philosophy, music and gardening, ...

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Octrooi- en evenementenkalender

Kijk voor de exacte tijdstippen en locaties op www.rvo.nl/octrooiagenda

Vrijdag 1 februari 2019: Workshop: Basis van intellectueel eigendom, Apeldoorn Donderdag 7 februari 2019: Workshop: Basis van intellectueel eigendom, Eindhoven Vrijdag 8 februari 2019: Workshop: Masterclass Octrooien, Zwolle Maandag 11 februari 2019: Workshop: Intellectueel eigendom-strategie voor mkb, Assen Vrijdag 18 februari 2019: Workshop: Zelf op zoek in octrooidatabanken, Eindhoven Donderdag 28 februari 2019: Workshop: Basis van intellectueel eigendom, Amsterdam Dinsdag 12 maart 2019: Workshop: Basis van intellectueel eigendom, Arnhem Donderdag 14 maart 2019: Workshop: Zelf op zoek in octrooidatabanken, Leeuwarden Vrijdag 15 maart 2019: Workshop: Slim omgaan met kennis bij samenwerking, Apeldoorn Donderdag 21 maart 2019: Workshop: Intellectueel eigendom-strategie voor mkb, Roermond Maandag 25 maart 2019: Workshop: Basis van intellectueel eigendom, Rotterdam Dinsdag 26 maart 2019: Workshop: Masterclass Octrooien, Groningen Maandag 1 april 2019: Workshop: Zelf op zoek in octrooidatabanken, Rotterdam Dinsdag 2 april 2019: Workshop: Intellectueel eigendom-strategie voor mkb, Apeldoorn Donderdag 4 april 2019: Workshop: Basis van intellectueel eigendom, Assen Maandag 8 april 2019: Workshop: Intellectueel eigendom-strategie voor mkb, Rotterdam Donderdag 11 april: Workshop: Slim omgaan met kennis bij samenwerking, Eindhoven Maandag 15 april: Workshop: Slim omgaan met kennis bij samenwerking, Leeuwarden Donderdag 18 april: Workshop: Zelf op zoek in octrooidatabanken, Arnhem Donderdag 9 mei: Workshop: Intellectueel eigendom-strategie voor mkb, Groningen Vrijdag 10 mei: Workshop: Basis van intellectueel eigendom, Apeldoorn Maandag 13 mei: Workshop: Slim omgaan met kennis bij samenwerking, Rotterdam Vrijdag 17 mei: Workshop: Masterclass Octrooien, Eindhoven Maandag 20 mei: Workshop: Zelf op zoek in octrooidatabanken, Assen Dinsdag 28 mei: Workshop: Basis van intellectueel eigendom, Amsterdam

Octrooicentrum Nederland (OCNL) in 2018

In het jaar 2018 werden er onder de Rijksoctrooiwet 1995, 2.519 nieuwe Nederlandse octrooiaanvragen ingediend.

Hiervan werden er 1.694 (67%) in het Engels opgesteld (tegenover 60% in 2017).

Van het totaal van Nederlandse octrooiaanvragen kwamen er 449 (2017: 374) uit het buitenland. Kortom, 82% van de Nederlandse aanvragen heeft een Nederlandse herkomst terwijl 18% van die aanvragen uit het buitenland komt.

Van het totale aantal aanvragen werd 83% (2.111 stuks) elektronisch ingediend.

In 2018 werden 1.972 Rijksoctrooien verleend.

Het aantal (door het Europees Octrooibureau) verleende Europese octrooien waarin Nederland werd aangewezen als land waar dat octrooi geldig zou moeten worden, bedroeg 124.216 stuks. Hierop werden door octrooihouders 28.650 (voor de validatie in Nederland vereiste) vertalingen ingediend (2017: 24.357 stuks). Het vervalpercentage komt hiermee op 77% (2017: 76%), goed verklaarbaar gegeven de nog steeds wassende stroom van verleende Europese octrooien.

Het totaal aantal levende (en te beheren) rechten in Nederland ultimo 2018, als opgenomen en in te zien in het wettelijke (digitale) octrooiregister, is uitgekomen op 213.408 stuks. In 2017 ging het om een totaal van 188.893 stuks (ter vergelijking: vijf jaar geleden, in 2014, ging het nog om 154.570 stuks).

Van dit totaal van 213.408 ultimo 2018 zijn er 196.994 (2017: 172.642) stuks van Europese origine en hebben er 16.151 (2017: 15.973) stuks een puur Nederlandse herkomst. Daarnaast zijn er 263 aanvullende beschermingscertificaten geldig, verleend op hetzij een Rijks- hetzij een Europees octrooi.

Het aantal wereldwijde aanvragen dat OCNL ontving als 'receiving office' onder het Patent Cooperation Treaty (PCT) bedroeg over het afgelopen kalenderjaar 919 stuks; daarvan werden er 896 online ingediend (97%).

Beleidsevaluatie Nederlandse Intellectueel Eigendomsbeleid

In de periode oktober 2017 - maart 2018 heeft onderzoeksbureau Technopolis in opdracht van het Ministerie van Economische Zaken en Klimaat (EZK) de periodieke beleidsevaluatie van het Nederlandse Intellectueel Eigendomsbeleid (hierna: IE-beleid) over de periode 2012-2017 uitgevoerd.

In de evaluatie stond de vraag centraal of het Nederlandse IE-beleid op doeltreffende en doelmatige wijze bijdraagt aan de versterking van het innovatievermogen van de Nederlandse kenniseconomie. Daarnaast is gekeken naar de toekomstbestendigheid van het IE-stelsel, in het licht van maatschappelijke, technologische en internationale ontwikkelingen.

De 'Periodieke Beleidsevaluatie van het Nederlandse Intellectueel Eigendomsbeleid' is op 9 november 2018 door Minister Wiebes van EZK aangeboden aan de Tweede Kamer. Voor de evaluatie zie <u>hier</u>.

In de <u>begeleidende brief</u> aan de Kamer (Tweede Kamer, vergaderjaar 2018–2019, 30 635, nr. 5) is Minister Wiebes ingegaan op de conclusies en aanbevelingen die in het evaluatierapport staan vermeld; ook besteed hij in de brief aandacht aan de wijze waarop hij invulling wil geven aan deze aanbevelingen.

De beleidsevaluatie is door de Tweede Kamer geagendeerd voor het Algemeen Overleg Bedrijfslevenbeleid op 31 januari 2019.

Leidraad wettelijk advies

Indien twijfels bestaan over de geldigheid van een Nederlands octrooi geeft Octrooicentrum Nederland (OCNL) desgevraagd advies over de geldigheid ervan. In de 'Leidraad wettelijk advies ex art. 84 Row 1995' staat aangegeven waaraan een adviesverzoek moet voldoen en hoe vervolgens het advies tot stand komt.

Na indiening van een Nederlandse octrooiaanvraag voert een examiner van OCNL of het Europees Octrooibureau een nieuwheidsonderzoek uit. Op basis van de gevonden documenten stelt de examiner tevens een opinie op over de nieuwheid en inventiviteit van de claims van de octrooiaanvraag. De aanvrager krijgt daarna ten minste twee maanden de gelegenheid om zijn conclusies aan te passen. Ongeacht de gevonden documenten en de opinie van de examiner (en ongeacht de eventuele aanpassingen van de aanvrager) wordt na 18 maanden octrooi verleend. De octrooiverlening in Nederland is daarmee dan ook laagdrempelig, eenvoudig en goedkoop.

Echter, bij derden kan onzekerheid bestaat over de geldigheid of de grenzen van de geoctrooieerde uitvinding. De adviesprocedure komt derden hierin tegemoet. Het doel van de adviesprocedure is om een snelle, eenvoudige en goedkope weg te bieden waarlangs inzicht kan worden verkregen in de (al dan niet gedeeltelijke) geldigheid van het octrooi. Het advies is bovendien verplicht indien bij de rechter een nietigheidsprocedure wordt gestart.

Mede op verzoek van de Orde van Octrooigemachtigden heeft OCNL een 'Leidraad wettelijk advies' opgesteld. De Leidraad geeft een overzicht van het verloop van de adviesprocedure. Het biedt onder meer inzicht in de vereisten die worden gesteld aan een adviesverzoek, het indienen van verweer met een eventueel hulpverzoek, het indienen van aanvullende stukken, vertegenwoordiging van partijen, etc. Voor de leidraad wettelijk advies zie <u>hier</u>.

Reeds uitgebrachte adviezen kunt u vinden op de website van OCNL, zie <u>hier</u>. Via het octrooidossier van betreffende octrooien (te raadplegen via het octrooiregister) kunt u voorbeelden vinden van adviesverzoeken, verweren en een indruk krijgen van het verloop van een adviesprocedure.

Voor vragen over de adviesprocedure kunt u contact opnemen met Octrooicentrum Nederland.

Apothekersvrijstelling

Op 18 december 2018 is het besluit houdende vaststelling van het tijdstip van inwerkingtreding van artikel 53, derde lid, tweede volzin, van de Rijksoctrooiwet 1995 geplaatst in het Staatsblad (<u>Stb. 2018, 469</u>). Met de plaatsing van dit besluit treedt de apothekersvrijstelling op 1 februari 2019 in werking. De apothekersvrijstelling vormt een uitzondering op het uitsluitend recht van de octrooihouder zoals bepaald in artikel 53 van de Rijksoctrooiwet 1995 en maakt het voor de apotheker mogelijk om in individuele gevallen een geoctrooieerd geneesmiddel te bereiden voor een individuele patiënt op medisch voorschrift, zonder toestemming van de octrooihouder. De apothekersvrijstelling was weliswaar onderdeel van de Rijksoctrooiwet 1995, maar was niet inwerking getreden omdat deze bepaling destijds enkel uit harmonisatieoverwegingen in het kader van het toenmalige (uit 1975 stammende maar nooit in werking getreden) Gemeenschapsoctrooiverdrag was opgenomen. Om de apothekersvrijstelling alsnog in werking te laten treden is een gezamenlijk <u>besluit</u> genomen door de Minister voor Medische Zorg en de Minister van Economische Zaken en Klimaat om de rechtszekerheid en duidelijkheid aangaande magistrale bereiding door de apotheker te vergroten.

Periodiek overleg met de Orde van Octrooigemachtigden

Tweemaal per jaar overleggen Octrooicentrum Nederland (OCNL) en de directie Innovatie en Kennis (EZK) met het bestuur van de Orde van Octrooigemachtigden. Naast het delen van diverse nationale en internationale ontwikkelingen wordt vooral gesproken over de gang van zaken op het gebied van octrooiverlening en octrooivoorlichting in Nederland. In het overleg van 16 november 2018 vormden het recente eindrapport van de evaluatie van het Nederlandse Intellectueel Eigendomsbeleid (hierna: IE-beleid) en een vernieuwde samenwerkingsovereenkomst tussen de Orde en OCNL de belangrijkste onderwerpen.

Eindrapport Beleidsevaluatie

Het eindrapport van de beleidsevaluatie door Technopolis is met een begeleidende brief naar de Tweede Kamer gezonden. Er worden vier hoofdonderwerpen onderscheiden: De perceptie van IE in de samenleving; het faciliteren van de gebruiker in bijzonder het MKB; verbetering van het wettelijk systeem en de toekomstbestendigheid van het octrooisysteem.

Met het bestuur van de Orde werd vooral doorgesproken over de behoefte aan strategisch advies bij het MKB en de wijze waarop van de kant van OCNL voorlichting gegeven wordt. Van belang is dat er daarbij een duidelijke taakomschrijving komt voor OCNL. De MKB-er moet in staat zijn strategisch advies in te winnen, bijvoorbeeld bij octrooigemachtigden; als opstap heeft deze MKBer elementaire basiskennis nodig die vooral bij OCNL verkregen kan worden.

Voorts werd gesproken over de timing van de wetswijzigingen die worden aangeroerd in de beleidsevaluatie. De Orde is bereid daarvoor de nodige input te leveren. De timing hangt nog af van de ontvangst van de evaluatie in de Tweede Kamer. Op een aantal mogelijke wetswijzigingen werd wat dieper ingegaan. Duidelijk naar voren kwam dat veel afhangt van de modaliteiten van de afzonderlijke wijzigingsvoorstellen. Het is nodig om een aantal voorstellen in detail uit te werken om deze effectief te kunnen bespreken op bijvoorbeeld een voor dat doel georganiseerd symposium.

Samenwerking Orde met OCNL

Een tweede belangrijk onderwerp van het overleg was de voorgenomen nieuwe samenwerkingsafspraak tussen OCNL en de Orde. Een dergelijk 'Memorandum of Understanding' (MoU) heeft in principe tot doel om de diverse gezamenlijke inspanningen te bevestigen en waar nodig te verduidelijken. De MoU is bedoeld als opvolger van het aloude convenant uit 2006. De eerste schriftelijk versie van zo'n MoU is nog voor verbetering vatbaar. Er is bijvoorbeeld verduidelijking nodig over de rol van OCNL waar het gaat om strategisch advisering (zie hierboven) en over de concrete afspraken om de toegankelijkheid van het octrooisysteem te verbeteren. Een klein comité zal het concept verder uitwerken.

Overige onderwerpen

Aandacht is besteed aan het *Benelux Patent Platform* (BPP) waarmee OCNL zijn octrooiprocessen ondersteunt. Ook voor 2019 staan er weer BPP-releases op de agenda. Zo beoogt OCNL in 2019 een forse uitbreiding van de (voor de klant zo belangrijke) MyPage functionaliteit tot stand te brengen. Voor de nabije toekomst van het BPP-systeem wordt strategisch nagedacht over de eisen die gesteld zouden moeten worden voor de verdere ontwikkeling van BPP. De klanten van OCNL worden ruim bij de ontwikkeling van deze toekomstvisie geconsulteerd.

Ook ging een lang gekoesterde wens in vervulling doordat OCNL een *Leidraad voor het Wettelijk Advies* kon presenteren. In deze Leidraad wordt de procedure voor het wettelijk advies omtrent de nietigheid van nationale octrooien in detail weergegeven. De leidraad werd goed ontvangen en zal breed gepubliceerd worden.

Voorts was de bescherming van persoonsgegevens (op basis van de Algemene Verordening Gegevensbescherming) onderwerp van gesprek. OCNL en de Orde zullen (al dan niet als onderdeel van de hierboven vermelde MoU) enige afspraken moeten maken omtrent de uitwisseling van persoonsgegevens van octrooigemachtigden. OCNL ging verder nog in op de nieuwe dienst '*IP Prediagnose*' die in Europees verband opgestart wordt en innovatieve MKB-bedrijven van meer basiskennis omtrent de (on)mogelijkheden van IE in het eigen bedrijf moet voorzien.

Daarnaast waren er korte updates ten aanzien van de databank octrooilicenties en de octrooikostencalculator.

Ten slotte werd een toelichting gegeven over de campagne om de nieuwe wet op de bedrijfsgeheimen onder de aandacht te brengen.

Rechtbank Den Haag beslist over teff-octrooien

In augustus 2018 berichtte de <u>Volkskrant</u> over een octrooi op teff. Het ging om twee Nederlandse en een Europees octrooi op teff-meel. De rechtbank Den Haag heeft eind november 2018 uitspraak gedaan over beide Nederlandse teff-octrooien.

Valgetal teff-meel

In de beide octrooien (NL1023977 en NL1023978) speelt de valtijd van een roerstaaf in een mengsel van teff-meel en water een grote rol. In het ene meel/water-mengsel zakt de roerstaaf sneller naar beneden dan in het andere mengsel. Het meten van de valtijd gebeurt volgens een standaardmethode (de zgn. Hagberg-methode). De gemeten valtijd (het zgn. 'Hagberg falling number' of kortweg: het valgetal) zou volgens het octrooi een indicatie zijn voor de bakkwaliteit van het teff-meel. Een teff-meel met een hoog of juist een laag valgetal zou volgens de octrooien niet tot goede bakproducten leiden. Het valgetal verbetert door narijpen van geoogst teff-graan. De octrooien claimen dan ook teff-meel met een valgetal binnen een bepaald bereik of een mengsel van teff-melen met verschillend valgetal.

Het meten van het valgetal van een meel is algemeen bekend, maar was nog nooit bij teff-meel uitgevoerd. Tussen partijen staat dan ook niet ter discussie dat het valgetal van een teff-meel nog nooit eerder was gemeten. Alleen in een bepaald Teff-Bericht van de octrooiaanvrager zelf werden valgetallen van teff-meel besproken. Octrooihouder stelde zich echter op het standpunt dat de ontvangers van het Teff-Bericht aan geheimhouding waren gebonden.

Procedure

De octrooihouder had een concurrent voor de rechter gedaagd wegens inbreuk. In het kader van het verweer dat de octrooien nietig zijn, is aan Octrooicentrum Nederland (OCNL) advies gevraagd over de geldigheid van beide teff-octrooien. OCNL achtte in haar advies beide octrooien geheel nietig, indien het Teff-Bericht voor indiening al openbaar bekend was. Indien echter het Teff-Bericht niet tot de stand van de techniek van de octrooien zou behoren, was de slotsom van OCNL dat de beide octrooien gedeeltelijk geldig waren.

Partijen hebben na het uitbrengen van het advies van OCNL de rechtbank verzocht om een getuigenverhoor te houden over het Teff-Bericht. Tegelijkertijd heeft octrooihouder zich in de rechtbank-procedure beperkt tot bescherming voor het bakken van producten met teffmeel(mengsels) met het juiste valgetal. Injera (een traditioneel Ethiopische bakproduct van teffmeel) werd hierbij expliciet uitgesloten als bakproduct vallend onder het octrooi.

Uitspraak rechtbank

In haar uitspraak heeft de Rechtbank Den Haag geconcludeerd (zie ook de bespreking in de rubriek 'Jurisprudentie' in dit Bijblad) dat het Teff-Bericht niet onder de geheimhouding valt. Vervolgens concludeert de rechtbank (op vergelijkbare gronden als OCNL) dat de beperktere werkwijzeconclusies van het hulpverzoek niet inventief zijn ten opzichte van het Teff-Bericht van de octrooiaanvrager. De rechtbank acht dan ook beide teff-octrooien nietig.

29e sessie van het Standing Committee on the Law of Patents (SCP)

Van 3-6 december 2018 vond in Genève de 28e sessie van WIPO's Standing Committee on the Law of Patents (SCP) plaats. De agenda bestond zoals de laatste jaren gebruikelijk uit het uitwisselen van informatie (waarbij voortdurend wordt herhaald dat het niet de bedoeling is dat de discussies direct leiden tot internationale harmonisatie).

Aan de orde kamen de navolgende onderwerpen:

- (i) exceptions and limitations to patent rights;
- (ii) quality of patents, including opposition systems;
- (iii) patents and health;
- (iv) the confidentiality of communications between clients and their patent advisors;
- (v) transfer of technology.

De discussie over 'Exceptions and Limitations to patent rights' werd voortgezet. Aan de orde waren met name reference document <u>SCP/28/3</u> met de navolgende inhoud: (i) overview of the regulatory review exception; (ii) objectives and goals of the regulatory review exception; (iii) the regulatory review exception and international legal framework; (iv) regional instruments and their implementation; (v) national implementation of the regulatory review exception; (vi) challenges faced by Member States in implementing the exception; and (vii) results of implementation of the exception. In de <u>Appendix</u> bij document SCP/28/3 wordt een overzicht gegeven van de verschillende nationale wettelijke systemen ter zake.

Op het terrein van 'quality of patents, including opposition systems' werd een 'sharing session' gehouden over de wijze waarop IP offices de kwaliteit van hun business verzekeren, zowel qua octrooiverleningsproces als via hun oppositiesystemen. Daarnaast was er een 'half-day conference' over de samenwerking tussen octrooibureaus ten aanzien van search en examination, inclusief het delen van informatie over 'corresponding foreign applications and grants'. Ook werd een 'further study on inventive step' besproken, zie document <u>SCP/29/4</u>.

Ten aanzien van het item 'Patents and Health' werd afgesproken dat gezorgd zal worden voor een regelmatige update van de publiekelijk toegankelijke databanken met octrooi-informatie over medicijnen en vaccins. Daarnaast zullen er ervaringen worden gedeeld over 'capacity building activities relating to negotiating licensing agreements'.

De SCP discussieerde verder over document <u>SCP/29/5</u> (Confidentiality of Communications between Clients and their Patent Advisors: Compilation of Laws, Practices and other Information): https://www.wipo.int/edocs/mdocs/scp/en/scp_29/scp_29_5.pdf WIPO zal in dit verband zorgen voor een continue update van de speciale website "Confidentiality of Communications between Clients and Their Patent Advisors". Over de verdere gang van zaken bestaat verdeeldheid. Zo bestaat bijvoorbeeld de opvatting dat dit issue moet worden overgelaten aan nationale wetgeving. Een andere opvatting is dat een discussie over een internationaal framework ten minste prematuur zou zijn.

Tot slot werd in de SCP stilgestaan bij 'patent law provisions that had contributed to effective transfer of technology, including sufficiency of disclosure' (zie document <u>SCP/29/6</u> en <u>SCP/29/6/CORR</u>.):

WIPO gaat door met het verzamelen van informatie ter zake, mede op basis van de input van lidstaten.

Voor een korte verslag van de 29e SCP, zie de Summary by the Chair.

De 30e SCP staat tentatief gepland voor 24 t/m 27 juni 2019.

EOB / Kort verslag 156e Administrative Council (AC)

De 158e Administrative Council (AC) van het Europees Octrooibureau (EOB) kwam laatstelijk bijeen in München, op 12 en 13 december 2018. Fungerend voorzitter Josef Kratochvil (CZ) meldde dat de contracten met de door de AC in oktober gekozen drie nieuwe vice-presidenten inmiddels rond zijn. Als bekend gaat het om Stephen Rowan (hij zal leiding geven aan het Directorate-General Patent Granting Process waar het end-to-end patent granting process, inclusief search, examination, publication, opposition en alle desbetreffende formalities, is ondergebracht), Nellie Simon (zij wordt verantwoordelijkheid voor het Directorate-General Corporate Services (Human Resources, Information Management, Finance, General Administration en Central Procurement) en om Christoph Ernst (hij wordt chef van het Directorate-General Legal/International Affairs dat zich richt op European en international co-operation, patent law en multilateral affairs, legal services, patent information en de European Patent Academy). De nieuwe vice-presidenten zullen op 1 januari 2019 starten met hun werkzaamheden.

EOB-President Antonio Campinos rapporteerde over onder andere de social dialogue, de kwaliteit van octrooiverlening, IT, de samenwerking met de EPC Member States en het door hem beoogde strategische plan (2019-2013). Dit plan wil hij, na voorafgaande intensieve consultatie van stakeholders, uiteindelijk ter goedkeuring voorleggen aan de AC in juni 2019. Voordien zal hij de AC (in maart 2019) om een opinie vragen over de dan voor te leggen 'main strategic orientations'. Campinos wil overigens op IT-terrein onmiddellijk stappen gaan zetten omdat de EOB-systemen (met name het backoffice) sterk verouderd zijn.

Intussen blijft het EOB goed scoren in termen van productie en 'timelineness'. Zo nam de voor een search gemiddeld benodigde tijd af van 4,8 maanden (2017) tot 4,4 maanden (2018). Oppositiezaken werden afgedaan in gemiddeld 18,6 maanden (tegenover 22,4 maanden in 2017). Alleen examination vergde in 2018 iets meer tijd: 22,2 maanden tegenover 22,0 maanden in 2017. Uit het 'User Satisfaction Research Programme' blijkt ook dat de 'user satisfaction' over de periode 2016-2018 in verband met de onderdelen Search, Examination, Opposition en Formalities op een stabiel, hoog niveau ligt.

Nederland informeerde tijdens de bespreking van het activities report van de President naar diens eerste reactie op de tijdens een hearing d.d. 5 december 2018 ingenomen positie van een Technical Board of Appeal waarmee deze Board te kennen gaf dat het oneens te zijn met de examining division om – onder expliciete verwijzing naar de een jaar eerder onder invloed van 'Brussel' geamendeerde Rule 28(2) EPC – een octrooiaanvraag inzake kleuring van paprika's af te wijzen. De desbetreffende Technical Board gaf als zijn oordeel dat Rule 28(2) EPC conflicteert met Article 53(b) EPC en dat in dat geval Article 53(b) - overeenkomstig Article 164 (2) EPC - prevaleert boven de door de AC onder invloed van 'Brussel' gewijzigde Rule. Het EOB - management zit duidelijk met de situatie in zijn maag en wilde tijdens de AC meeting niet inhoudelijk reageren; het geeft er de voorkeur aan om eerst het op schrift gestelde besluit van de Technical Board, met daarin de "full reasons", af te wachten. Naar verwachting komt dit besluit begin 2019 schriftelijk beschikbaar.

In het verlengde van het besluit van de AC tot 'modernisation of the EPO's employment framework' om méér flexibiliteit in het personeelsbeleid te creëren (met ook de mogelijkheid dat personeel voor een bepaalde tijd worden aangesteld) – in werking getreden op 1 april 2018 – heeft de President van het EOB conform afspraak (nu voor het eerst) een 'Orientation paper on recruitment' aan de AC doen toekomen. Daarbij gaat het erom dat een 'responsive workforce planning' verzekert dat in het personeelsbeleid (qua aantal fte's en qua competenties) beter rekening kan worden gehouden met wat het EOB gegeven zijn missie en doelstellingen nodig heeft. De AC heeft positief gereageerd op het orientation paper.

Verder is door het EOB een 'Orientation paper' over 'Future EPO Building projects' gepresenteerd. Het is de bedoeling dat het EOB in de toekomst een "modern working environment along with efficient and effective space management" zal hebben; de huidige huisvesting voorziet daarin gemiddeld genomen beslist nog niet. De fonkelnieuwe New Main in Rijswijk is daarentegen hèt voorbeeld van de state-of-the-art working environment dat het EOB voor ogen heeft. De AC heeft ook dit orientation paper positief onthaald.

Beide orientation papers staan in direct verband met het overall strategic plan 2019-2013 dat EOB-President Campinos in juni 2019 wil voorleggen aan de AC (zie hierboven). Op het gebied van 'appointments/elections' ging de AC unaniem akkoord met de benoeming van Deputy Chairman Josef Kratochvíl tot Chairman van de AC, per 1 januari 2019, voor een periode van drie jaar. Er waren geen tegenkandidaten. Kratochvíl volgt Christoph Ernst op die per 1 januari overstapt naar het EOB (zie hierboven). Begin 2019 volgt een 'call for candidates' voor het Deputy Chairmanship van de AC.

Onder 'Any Other Business' herinnerde Nederland vriendelijk aan de in het eerste kwartaal van 2018 aangehouden discussie over het streven van de AC (als expliciet neergelegd in zijn befaamde March 2016 Resolution) om het Council Secretariat onafhankelijker van het EOB en meer in dienst van de AC te doen functioneren. Destijds werd de discussie (over bijvoorbeeld een gentlemen's agreement ter zake) aangehouden omdat de AC het ermee eens was dat één van de hoofdrolspelers in dat verband (toenmalig EOB-President Battistelli) zijn opvolger hierbij niet voor de voeten wilde lopen. Nu zowel een nieuwe EOB-President als een nieuwe AC Chair hun stoelen hebben ingenomen, lijkt het een uiterst geschikt moment om het debat over het functioneren van het Council Secretariat (en daarmee in wezen over de verhouding tussen AC en het EOB) te hervatten.

Uitspraak Technische Kamer EOB

Op 5 december 2018 heeft een Technische Kamer van Beroep van het Europees Octrooibureau (EOB) tijdens een mondelinge hoorzitting in zaak T 1063/18 besloten dat de in 2017 geamendeerde (uitvoeringsregel bij het Europees Octrooiverdrag (EOV)) Rule 28 (2), waarin is bepaald dat producten verkregen middels een werkwijze van wezenlijk biologische aard uitgesloten zijn van octrooieerbaarheid, niet geldig is.

Deze hoorzitting was onderdeel van de beroepsprocedure tegen de afwijzing van een octrooiaanvraag op basis van Artikel 53 (b) EOV en Rule 28 (2). Volgens de Technische Kamer is Rule 28 (2) in strijd met artikel 53 (b) EOV zoals geïnterpreteerd door de Grote Kamer van Beroep in zaak G 2/12 en zaak G 2/13 en dat overeenkomstig artikel 164 (2) van het EOV de bepalingen van het EOV voorrang hebben boven uitvoeringsregels. Een door de aanvrager ingediend verzoek voor eventuele verduidelijking van de geldigheid van Rule 28 (2) door de Grote Kamer van Beroep werd door de Technische Kamer terzijde gelegd.

De Technische Kamer heeft hiermee ook expliciet afstand genomen van de interpretatieve verklaring van de Europese Commissie die ten grondslag ligt aan de in 2017 geamendeerde Rule 28 van het EOV. Rule 28 (2) EOV is in juli 2017 op verzoek van Administrative Council van het EOB geamendeerd nadat de Europese Commissie in haar 'Mededeling inzake bepaalde artikelen van <u>Richtlijn 98/44/EG</u> van het Europees Parlement en de Raad betreffende de rechtsbescherming van biotechnologische uitvindingen (2016/C 411/03)' heeft verduidelijkt dat het de bedoeling van de EU-wetgever was om producten die verkregen zijn door middel van wezenlijk biologische werkwijzen, uit te sluiten van octrooieerbaarheid. Deze Mededeling kwam overigens in reactie op de bovengenoemde uitspraken van de Grote Kamer van Beroep, waarin de Grote Kamer oordeelde dat de uitsluiting van octrooieerbaarheid, zoals verwoord in artikel 53 (b) EOV, niet ziet op producten die verkregen zijn middels een werkwijze van wezenlijk biologische aard. Het EOB had de Mededeling van de Europese Commissie (die overigens de steun kreeg van de Raad van de EU) juist overgenomen om harmonisatie en duidelijkheid in Europa op dit gebied in octrooirecht te waarborgen.

Met deze uitspraak van de Technische Kamer is de onduidelijkheid omtrent de octrooieerbaarheid van biologisch materiaal weer terug en staat dit onderwerp opnieuw hoog op de (politieke) agenda. In de Tweede Kamer zijn eind december 2018 <u>vragen</u> gesteld aan de Minister van Landbouw, Natuur en Voedselkwaliteit naar aanleiding van deze uitspraak.

Voor het verslag van de hoorzitting zie hier.

BIE 2019, nr. 1 Hof van Justitie van de Europese Unie 25 oktober 2018 Boston Scientific Ltd vs Deutsches Patent- und Markenamt

Artikel 2 Verordening (EG) 469/2009

Een stof die als integrerend bestanddeel is verwerkt in een medisch hulpmiddel in de zin van artikel 1, lid 4, van Richtlijn 93/42, en de werking op het menselijk lichaam van het hulpmiddel ondersteunt waarvan het onderdeel is, kan voor dit gebruik niet worden aangemerkt als geneesmiddel in de zin van Richtlijn 2001/83, ook al zou deze stof als zodanig kunnen worden aangemerkt indien zij afzonderlijk werd gebruikt. Een dergelijke stof kan dus niet binnen de werkingssfeer van Verordening nr.469/2009 vallen.

[Volledige uitspraak]

BIE 2019, nr. 2 Conclusie van de Advocaat Generaal Hof van Justitie van de Europese Unie 13 december 2018 Abraxis Bioscience LLC vs Comptroller General of Patents

Artikel 3(d) Verordening (EG) 469/2009

De Advocaat Generaal stelt voor om afstand te nemen van de teleologische uitlegging van artikel 3, onder d) van Verordening (EG) 469/2009 zoals gegeven door het Hof van Justitie van de Europese Unie in zaak C-130/11 (Neurim). In Neurim heeft het Hof de letterlijke uitlegging van artikel 3, onder d), van Verordening 469/2009 vervangen door een teleologische uitleg die uitgaat van de voorwaarde dat de vergunning voor het in de handel brengen van het product waarop de aanvraag voor een aanvullend beschermingscertificaat is gebaseerd de eerste is en gekoppeld is aan de beschermingsomvang van het octrooi. Een letterlijke uitleg van artikel 3, onder d), gelezen in samenhang met artikel 1, onder b), van Verordening 469/2009, impliceert dat het niet van belang is of deze vergunning al dan niet de eerste vergunning binnen de beschermingsomvang van het basisoctrooi is. Hoewel bij de uitlegging van de bepalingen van Verordening 469/2009 niet alleen mag worden uitgegaan van de bewoordingen ervan, maar ook de algemene opzet en de doelstellingen van de door deze verordening ingestelde regeling in de beschouwing moeten worden betrokken, is het Hof volgens vaste rechtspraak niet bevoegd om van een duidelijke en precieze tekst van een wetgevingshandeling van de Unie af te wijken. Dat geldt te meer wanneer, zoals in casu, het onderzoek van de doelstellingen en van de context van de betrokken bepaling en van de verordening waarin deze bepaling is neergelegd, steun biedt aan de letterlijke uitlegging. Indien het Hof de teleologische uitlegging van artikel 3, onder d) van Verordening 469/2009, zoals bepaald in Neurim, niet wil verlaten stelt de Advocaat Generaal subsidiar voor om slechts de beschermingsomvang van het basisoctrooi bij de uitleg van artikel 3(d) te betrekken in het uitzonderlijke geval dat een product krachtens Richtlijn 2001/82 al voor een therapeutische indicatie als diergeneesmiddel is toegestaan en vervolgens uit hoofde van Richtlijn 2001/83 een vergunning voor een nieuwe therapeutische indicatie als geneesmiddel voor mensen wordt afgegeven.

[Volledige Conclusie]

BIE 2019, nr. 3 Rechtbank Den Haag 21 november 2018 Ancientgrain B.V. vs Bakels Senior N.V.

Stand van de techniek

Bakels, die stelt dat het Teff-Bericht tot de stand van de techniek behoort en daaraan rechtsgevolgen verbindt, dient die stelling te onderbouwen en zo nodig te bewijzen. Een document wordt geacht openbaar toegankelijk te zijn wanneer het toegankelijk was voor het publiek, waarbij het voldoende is dat één persoon in theorie in de positie was om toegang te verkrijgen tot het document, tenzij die persoon gebonden is door een geheimhoudingsovereenkomst. Daarbij is niet van belang of 'het publiek' daadwerkelijk kennis heeft genomen van het document.

Naar het oordeel van de rechtbank (..) hebben de teff-telers niet kunnen en hoeven begrijpen dat zij de in het Teff-Bericht genoemde informatie vertrouwelijk moesten behandelen. Dit volgt in ieder geval niet rechtstreeks uit de in algemene bewoordingen gestelde geheimhoudingsclausule. Uit de mededeling dat reeds octrooi was aangevraagd, zouden de ontvangers van het Teff-Bericht juist hebben kunnen afleiden dat er geen belang meer was bij geheimhouding.

De verklaringen van de teff-telers die Bakels ter onderbouwing van het openbare karakter van het Teff-Bericht als getuigen heeft doen horen, wijzen evenmin op geheimhouding.

De rechtbank stelt dan ook vast dat bij gebreke van een op het Teff-Bericht toepasselijk (impliciet of expliciet) geheimhoudingsbeding, de informatie daarin openbaar toegankelijk was in mei 2003 en tot de stand van de techniek van de octrooien behoort.

Inventiviteit

Vervolgens staat ter beoordeling of de octrooien nietig zijn wegens het ontbreken van inventiviteit ten opzichte van het Teff-Bericht.

De vakman zal uit het Teff-Bericht begrijpen dat de valgetallen van teff blijkbaar moeten worden gemeten, dat meel met een laag valgetal gemengd moet worden met meel met een hoog valgetal om een goed bakresultaat te krijgen en dat Nederlands teff-graan narijpt (vgl. advies OCNL inzake NL 977, p. 10) (zie ook, BIE 2015, nr. 13). Een aantal (deel)kenmerken van conclusie 1 van hulpverzoek 977 en 978 worden in het Teff-Bericht niet ondubbelzinnig geopenbaard. Deze kenmerken worden hierna aangeduid als de "verschil-kenmerken".

Ter beantwoording staat vervolgens of, uitgaande van hetgeen in het Teff-Bericht is geopenbaard, uitvinderswerkzaamheid nodig is om te komen tot de geclaimde uitvindingen. (..) Bij de beantwoording van die vraag hebben partijen niet de *problem-and-solution* approach gehanteerd. De rechtbank zal dit evenmin doen, maar hierna de inventiviteit aan de hand van de verschilkenmerken beoordelen.

- De uitsluiting van injera is kennelijk gedaan om de octrooien af te bakenen van de (andere) stand van de techniek, nu bereiding van injera met teff-meel in Ethiopië een oude traditie is. Gesteld noch gebleken is dat die afbakening de conclusies inventief maakt ten opzichte van het Teff-Bericht.
- Nu nawerking zich steeds voordoet zoals in het Teff-Bericht aangegeven, acht de rechtbank narijping met een factor 0,01 inherent in het Teff-Bericht geopenbaard.
- Nu het Teff-Bericht openbaart dat het valgetal van het teff-meel van belang is voor de bakkwaliteit, en dat een mengsel van meel met een laag valgetal en meel met een hoog valgetal goed bakt, is dit technisch effect niet langer onverwacht en kan dit conclusie 1 van hulpverzoek 977 niet inventief maken.
- De geclaimde methode voor het bakken van een product (..), is een zeer gangbare bakmethode die tot de algemene vakkennis behoort.
- Het mengen van twee melen, dat geacht kan worden deel uit te maken van de algemene vakkennis, kan de conclusie niet inventief maken.

Nu geen van de verschil-kenmerken inventiviteit verleent, en ook de combinatie daarvan voor de hand liggend is, moeten conclusies 1 van hulpverzoeken 977 en 978 niet geldig, want niet inventief ten opzichte van het Teff-Bericht, worden geacht.

[Volledige uitspraak]

BIE 2019, nr. 4 4 Rechtbank Den Haag 21 november 2018 Construction Diffusion Vente Internationale SA vs Impro Technologies Europe B.V. en Alphatronics B.V.

Inventiviteit

De rechtbank is van oordeel dat EP 006 (NL) in de huidige, door Construction Diffusion Vente Internationale (CDVI) voorgestane, vertaling en uitleg van de conclusies, aan nietigheid bloot staat omdat het octrooi niet inventief is ten opzichte van de stand van de techniek, die is weergegeven in Figuur 1 van het octrooi en de algemene vakkennis.

Het verschil-kenmerk tussen conclusie 1 en de inrichting van figuur 1 is een sleuf die zich uitstrekt van een van de randen van de voorkant van de metalen beschermingsbehuizing (..) richting het centrum van de voorkant. Het technisch effect van dit verschil-kenmerk is, dat bij gelijkblijvend vermogen de elektronische sleutel op grotere afstand afgelezen kan worden door een antenne (..). De natuurkundige verklaring voor het optreden van dit effect van het verschil-kenmerk is, dat een sleuf die zich uitstrekt vanaf de rand van de behuizing er voor zorgt dat de Eddy currents een langere weg moeten volgen, daardoor sterk in kracht afnemen en zelfs positief gaan bijdragen aan de flux van de antenne.(..)

Naar het oordeel van de rechtbank volgt uit dit technisch effect dat het op te lossen probleem is: 'het verschaffen van een leesinrichting met een metalen beschermingsbehuizing die in staat is om een elektronische sleutel op relatief grote afstand van de leesinrichting uit te lezen zonder daarbij de beschermfunctie van de behuizing aan te tasten'. Impro c.s. betoogt dat het op te lossen probleem is 'hoe een antenne goed beschermd op te sluiten in een metalen behuizing waarbij magnetische flux minder door die behuizing wordt geabsorbeerd vanwege Eddy currents'. Daarbij verliest zij uit het oog dat zij in de probleemstelling niet alleen een technisch effect opneemt, maar eveneens de verklaring voor dat effect, en daarmee een aanwijzing naar de oplossing.

CDVI heeft niet weersproken dat de Feynman Lectures alom bekend zijn (naar de rechtbank begrijpt: onder natuurkundigen en elektrotechnici) en op de prioriteitsdatum tot de algemene vakkennis van de vakman behoorden. De Feynman Lectures vermelden dat hier Eddy currents in het spel zijn en geven een oplossing om Eddy currents drastisch te verminderen (..). De vakman weet daardoor dat in een metalen plaat die in het magnetisch veld van de antenne is geplaatst Eddy currents optreden en dat die currents aanzienlijk worden verminderd of geneutraliseerd door de metalen plaat te voorzien van een paar sleuven vanaf een van de randen. De vakman kent dat natuurkundig fenomeen en de oplossing ervoor overigens ook uit het Von Waltenhofen experiment, dat eveneens tot zijn algemene vakkennis behoort.

Gesteld voor het probleem om de leesinrichting van figuur 1 zo te wijzigen dat een kaart op grotere afstand gelezen kan worden zal de vakman met deze algemene vakkennis zonder inventieve arbeid onmiddellijk herkennen dat Eddy currents de oorzaak van de verzwakking van de flux zijn en dat de negatieve werking daarvan afneemt door één of, voor een groter effect, meer sleuven vanaf een van de randen van de metalen plaat aan te brengen.

Dat dit in de stand van de techniek een bekende oplossing voor het probleem van fluxverzwakking door Eddy currents is, wordt bevestigd door JP 123, NL 369 en US 989. (..)

Dit brengt de rechtbank tot de slotsom dat conclusie 1 van EP 006 vernietigbaar is omdat het inventiviteit ontbeert.

[Volledige uitspraak]