

TINE SOMMER

Can Law Make Life (too) Simple?

*From gene patents to the patenting of
environmentally sound technologies*



DJØF PUBLISHING

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of environmentally sound technologies

For Brage

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DJØF Publishing
Copenhagen 2013

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From gene patents to the patenting of environmentally sound technologies

1. edition

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Jurist- og Økonomforbundets Forlag

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Photo: Tine Sommer (La Jolla, San Diego)
Cover: Bo Helsted
Print: AKAPRINT, Tilst

Printed in Denmark 2013
ISBN 978-87-574-3119-3

Published with support from Dreyers fond

dreyersfond

This thesis was accepted by the School of Business and Social Sciences at Aarhus University for defence of the doctoral degree in Law (Dr. jur.).

Aarhus School of Business and Social Sciences, Aarhus April 24 2013

Svend Hylleberg
Dean

The public defence will take place at the Department of Law, Aarhus University,
on Friday 30 August 2013 at 1 pm
at Juridisk Auditorium, building 1343/auditorium 275, Aarhus University.

Sold and distributed in Scandinavia by:

DJØF Publishing
Copenhagen, Denmark
Email: forlag@djoef.dk
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Preface

I started the work which forms the basis for this thesis back in 1998 when I was working at the Aarhus School of Business, first as an assistant professor, then as associate professor and now as professor (temporary). The idea of carrying out an empirical case study arose in 2004 during a four-month sabbatical at Vanderbilt Law School, Vanderbilt University, Tennessee. The idea has evolved over the years as my skills have developed, and the case study has been designed and redesigned accordingly. My theoretical knowledge of US patent law was acquired at Vanderbilt University Law School and particularly at Columbia Law School, Columbia University, New York, where I spent a seven-month sabbatical in 2008 and a three-month sabbatical in 2011. During the periods I spent in New York I was warmly welcomed by Professor Harold Edgar, and my special thanks are due to him for his inspiring teaching and his willingness to discuss the many difficult areas of patent law; he has the ability to ask challenging questions which prompt thoughtful reflection. In 2009 I was also privileged to spend two weeks at the New York University School of Law at the invitation of Professor Rochelle Dreyfuss.

In the course of the work on my thesis I have received valuable help from colleagues. My particular thanks are due to Professor Ellen Margrethe Basse, of Aarhus University, for always being willing to put aside whatever she has been doing in order to help. I would also like to thank Cita Kristensen, who has been ever-ready to help with proof reading and with practical issues, and Steven Harris who has reviewed the use of English. I also owe a considerable debt to Henrik Tværmoose, Librarian at Aarhus Universitet; who has always been willing to help with the many demands made or in course to my work on this thesis, ever since its start in 1998. I have also received help from law students Anders Yde, who helped with the initial patent searches, and Anne Hummersgaard Hansen HA(jur), who has compiled the bibliography, table of cases and table of legislation.

Above all, my family has been an invaluable support. Work on this thesis has been a constant part of our lives for many years and it has inevitably influenced our family life. My special thanks are due to Lili, for always believing in me, pointing me in the right direction, and teaching me to persist.

Preface

I must also give special thanks to my children, Silje, Emil and Olav. In 2004, 2008 and again in 2011, they have adapted by fitting into the US school system and sporting life. I have had the pleasure of having both my daughter Silje and my son Emil help structure the materials from the search results, not least the many patent documents. I am grateful for the way they have accepted the many years during which I may have been distracted by this work.

This thesis would never have seen the light of day without my supporter and soul-mate, Brage. Thank you for your inspiration, boundless patience and invaluable help in translating the language of genetics into legal concepts. The many evenings with data bases, patent applications and medical textbooks have been essential to the approach to the thesis. Not least the many discussions about the reach of patent law and its justification in biomedical research have been both interesting and instructive.

Needless to say, while I am grateful for all the help I have received, any errors are entirely my own.

Finally, it is my pleasure to thank the many external funds which have supported my work. I have received support from the Danish Council for Independent Research | Social Sciences (2004, 2006 and 2008); from the Genome Research Project: Comparative Genomics focusing on man and pig (2004); Frode and Norma Jacobsens' Foundation (2004); Axel H's Travel Foundation (2004 and 2011); and Julie von Müllen's Foundation (2011).

The references to the literature in the thesis have been updated frequently. However, since April 2012 only references that have come up on alerts (blogs) have been added. The most recent development is that an agreement on a unitary patent has been postponed indefinitely, after the Member States deleted three paragraphs from the draft agreement, following pressure from the United Kingdom, without consulting the European Parliament. The thesis has been updated to take account of the Council Decision of 29 June 2012, but this latest development has not been taken into account.

Aarhus 4 July 2012

Tine Sommer

Summary in Danish

Afhandlingens kerne er den moderne patentret, således som den er blevet udfordret af især den bioteknologiske udvikling. Patentretten betragtes imidlertid ikke isoleret i afhandlingen, men miljøretlige, handelsretlige og EU-retlige aspekter inddrages med det formål at placere patentretten i en global og dynamisk virkelighed. Det for afhandlingen overordnede spørgsmål er udtrykt i afhandlingens titel. Afhandlingen bærer hovedtitlen '*Can law make life (too) simple?*' I afhandlingen adresseres humane genpatenter, patenter i dyreriget og klimaforandrings pres på patentregimet. Formålet har været at undersøge den ekspansion af patentrettens genstand, som områderne har foranlediget. Afhandlingen er styret af flere underspørgsmål til overskriften såsom patentering af komplekse biologiske systemer hos mennesker og dyr samt teknologiens pres på patentinstitutionen. Skal der reageres i lovteknisk henseende på teknologiske udviklinger, eller skal udviklingen i takt med behovet herfor forenes med den eksisterende lovgivningsmæssige ramme af patentmyndigheder og domstole? Ved eksempelvis komplekse biologiske systemer synes en detailregulering at komme til kort med den følgevirkning, at den forsimplede (detaljerede) lovtekst ikke favner de komplekse biologiske systemer, men får en statisk indvirkning på samspillet mellem teknologi og patentretlig beskyttelse.

Afhandlingen belyser patentretten i en 'multilevel' og fragmenteret kontekst herunder også kritisk i relation til den tiltagende EU-retlige indblanding i den formelle og materielle patentret. Tilgangen er baseret på 'multilevel' regulering, hvorefter patentretten i det globale samspil henter sine kilder fra det internationale, regionale samt nationale niveau. Her har den EU-retlige regulering formålet at skabe kaos på det regionale niveau med tab af patentrettens legitimitet til følge. Det anbefales, at patentretten hjemvises til det større forum i Den Europæiske Patent Organisation og videreudvikles gennem globale normer som rettesnor for det internationale samfund. Her har især den amerikanske Supreme Court været inspirerende, og sammenligningen mellem den europæiske detailregulering og den amerikanske mere doktrinbaserede tilgang har bevirket, at afhandlingens anbefaling hælder til brede penselstrøg. Patentrettens forankring i doktriner, som regulerer den patentretlige genstand,

har en større fleksibilitet og dynamisk fremtidssikring af patentinstitutionen. Dette illustreres konkret med direktiv 98/44/EC om retlig beskyttelse af bioteknologiske opfindelser, herunder direktivets tilgang og ordlyd i forhold til patentering af DNA sekvenser, embryonale stamceller, og beskyttelsesomfang for DNA sekvenser.

Afhandlingen er inddelt i 5 dele. *Del 1* benævnt 'MULTILEVEL REGULERING OG NYE TEKNOLOGIER' indeholder kapitlerne 1-4. KAPITEL 1 introducerer afhandlingens genstand og udviklingen inden for afhandlingens tre områder: patent på humane gener, patentering af opfindelser vedrørende dyr og teknologier inden for klimaforandring. Kapitlet fastsætter afhandlingens overordnede ramme såvel som teori og metode, herunder afhandlingens kildemateriale. Spørgsmålet i kapitel 1 er hvilke organer, der er bedst egnet til at håndtere kollisioner mellem patentretlig beskyttelse og nye teknologier. Særligt tabel 1.1 i kapitel 1 forsøger at illustrere de mange hensyn, som gør sig gældende i en global sammenhæng baseret på en polycentrisk tilgang til retten. Disse hensyn foreslås forenet i en global patentretlig norm, som udspringer af og baseres på det globale (tidligere miljøretlige) princip '*common concern of mankind*', som henvender sig til de globale '*commons*'. KAPITEL 2 behandler den teknologiske udvikling i kontekst af detailregulering. Kapitlet indfører læseren i den teknologiske verden som baggrund for især kapitel 7's empiriske casestudy. Det forklares, hvorledes lovgivningens ramme skal forstås ud fra en genetisk indførelse i eksempelvis 'hvad er et gen? Hvilken genetisk information indeholder gener? Hvilke funktioner har et gen? Desuden introduceres nye teknologier i biomedicinsk forskning. Særligt forholdet mellem bioteknologi, genteknologi, nanoteknologi, syntetisk biologi og kemikalier forsøges illustreret i figur 2.1. KAPITEL 3 belyser afhandlingens fokus på multilevel regulering ud fra en gennemgang af de for afhandlingen relevante aktører (herunder EU, EPO, WIPO, USPTO). Her er det især EU's optræden på den internationale og regionale scene, som har interesse. Med patentretten som eksempel pointeres det, at EU udvider sin kompetence internationalt såvel som regionalt gennem etableringen af, hvad forfatteren benævner '*distinct European system of public international law and regional law*' forstået således, at EU-retten synes at fremtræde som ophøjet ret på såvel nationalt, regionalt og internationalt niveau inden for patentrettens område. KAPITEL 4 afslutter *Del 1* med ud fra patentrettens moralbegreb at illustrere, hvorledes patentretten på det regionale niveau er påvirket af EU hensyn, som kolliderer med den Europæiske Patentkonvention. Hvornår har den ene, og hvornår har den anden myndighed kompetence til at definere indholdet af direktiv 98/44/EC om retlig beskyttelse af bioteknologiske opfindelser? Her er særlig spørgsmålet om embryonale stamceller og direktivets

artikel 6, stk. 2 genstand for behandling. Spørgsmålet er, om der ikke *netop her* er behov for en forsimpning (can law make life too simple?). Udviklingen går dog i retning af yderligere ‘kompetence uorden’ med EU patentet, idet der foruden EPO, herefter bliver tale om et EU i flere tempi, nemlig EU(2) og EU(25) som følge af den valgte fremgangsmåde for forstærket indbyrdes samarbejde, hvorefter hjemmelen for vedtagelsen af EU patentet (TFEU artikel 329, stk. 1) muliggør, at ikke alle medlemsstater tilslutter sig samarbejdet.

Afhandlingens *Del II* er benævnt ‘DET HUMANE GENOM’. Kapitlerne 5-7 fokuserer alle på humane genpatenter. KAPITEL 5 diskuterer TRIPS-aftalens *ikke-diskriminationsprincip*, som er kodificeret i TRIPS-aftalens artikel 27, stk. 1. Det antages, at TRIPS-aftalen, som ikke definerer begrebet ‘opfindelse’, har overladt til medlemmerne at bestemme hvad, der er genstand for patentering. Dog begrænses dette råderum af *ikke-diskriminationsprincippet*, således at hele produktgrupper ikke kan undtages (for eksempel lægemidler). Hermed hindrer TRIPS-aftalen ikke en afgrænsning af hvilke genstande, der udelukkes fra patentbeskyttelse, for eksempel fordi substansen betragtes som værende et naturligt fænomen. Kapitel 5 belyser endvidere humane DNA sekvenser ud fra henholdsvis den europæiske retstilstand og den amerikanske retstilstand. Forskelligt fra den europæiske detailregulering indeholder amerikansk ret ikke detailregler for patenteringen af humane DNA sekvenser, men baseres på domstolspraksis. Den nye udvikling foranlediget af den amerikanske Supreme Court – hvorefter patenteringen af gener revurderes – stilles over for den europæiske praksis, herunder især CJEU, hvorefter afgrænsninger finder sted gennem en præcisering af beskyttelsesomfanget. Afhandlingens empiriske casestudy indledes med baggrundsinformation i KAPITEL 6. Det empiriske studium er baseret på en behandling af patentaktiviteten inden for seks sygdomme, hvoraf de fire første sygdomme Huntington, Spinal Muskel Atrofi, Canavan, og Cystisk Fibrose, som er forårsaget af en mutation i et enkelt gen, er kendetegnet som enkeltgen sygdomme, mens de to sygdomme Alzheimers og Parkinson er karakteriseret ved at være multifaktorielle sygdomme, hvilket indebærer, at flere faktorer, eksempelvis en kombination af små variationer i generne i samspil med miljøfaktorer, kan have indflydelse på, hvorvidt sygdommen kommer til udtryk. Kapitel 6 indeholder en gennemgang af sygdommene, samt angiver patentaktivitetens state-of-the-art inden for hver enkelt sygdom baseret på en gennemgang af den juridiske litteratur. KAPITEL 7 bidrager til den juridiske litteratur med et empirisk studium af i alt 1590 patentansøgninger fordelt på de udvalgte sygdomme. 39 % af de undersøgte patentansøgninger førte til et patent, 38,4 % blev afvist og 22,6 % er stadig verserende. Patentdokumenterne er fremkommet på baggrund af søgninger foretaget af den danske patent- og varemærkestyrelse

(hhv. i 2004, 2005, 2007, 2009, 2011, og 2012). Analysen er inden for hver sygdom (eksempelvis Huntington, Canavan osv.) inddelt i fire undergrupper. De fire undergrupper er benævnt sygdomsgenet, sygdomsprocessen, stamceller og en sidste gruppe benævnt highlights, som kan være forskellig fra sygdom til sygdom. De væsentligste konklusioner fra det empiriske studie er tilknyttet de nye RNAi-teknikker (miRNA, siRNA), som udfordrer det traditionelle genpatent og som i afhandlingen tages til indtægt for, at ordlyden i direktiv 98/44/EC er for statisk og uegnet til at imødekomme nye udviklinger i biomedicinsk forskning. Desuden stilles der spørgsmål ved den omfattende brug af 'laundry lists', hvorefter patentansøger ikke indskrænker sin ansøgning til en konkret sygdom, men derimod i langt hovedparten af de undersøgte patenter inddrager en lang række af sygdomme, som kan have mere eller mindre tilfælles med hovedsygdommen.

Afhandlingens *Del III* er benævnt 'DYRERIGET'. Den består af et kapitel – KAPITEL 8, som gennemgår retstilstanden for patentering i relation til dyr, og ligesom kapitel 7 indeholder kapitlet en empirisk analyse, hvor aktivitet i relation til grisen er behandlet. Særligt paralleliteten om forbuddet mod patent på overvejende biologiske fremgangsmåder til forædling af planter eller dyr trækkes videre til kapitel 10. En fremgangsmåde er overvejende biologisk, når den i sin helhed beror på naturlige fænomener som krydsning eller udvælgelse. Derimod er naturlige biologiske processer i relation til mennesker ikke som sådan undtaget fra patentering.

Afhandlingens *Del IV* belyser 'PATENTINSTITUTIONEN SOM 'BELL-WETHER' FOR GLOBALE PROBLEMSTILLINGER'. Denne del indeholder to kapitler – kapitel 9 og kapitel 10. KAPITEL 9 ser på retsudviklingen som en bølgemetafor i form af små retsbølger. Lovgivningen gentager sig selv i små bølger, og det konkluderes, at lovgiver må have fortiden præsent for der gribes ind med nye evt. forhastede lovgivningsmæssige tiltag. Konkret behandles klimaforandringernes indvirkning på patentretten. Er det nødvendigt at vedtage klimavenlige incitamentter gennem en ændring af patentlovgivningen – eller er lovgivningen i stand til at absorbere nye udfordringer? Endelig afsluttes afhandlingen i KAPITEL 10 med en opsummering af resultaterne og med et forslag til at bevare patentretten dynamisk og fleksibel. Her er det især multilevel reguleringen og den pluralistiske retskildetilgang, som søges forenet gennem etableringen af en *global offentlig orden* inden for patentrettens område hvilende på det i kapitel 1 introducerede internationale miljøretnlige princip '*Common Concern of Mankind*'.

Table of Abbreviations

AD	Alzheimer's disease
CAFC	Court of Appeals for the Federal Circuit (US)
CBD	Convention on Biological Diversity
CD	Canavan's disease
CF	Cystic fibrosis
CJEU	Court of Justice of the European Union/ Court of Justice
DNA	Deoxyribonucleic acid
EBA	Enlarged Board of Appeal of the European Patent Office
EPC	European patent Convention
EPO	European Patent Office/Organisation
EU	European Union
HD	Huntington's disease
hESC	Human embryonic stem cell
HUGO	Human Genome Organisation
ICTSD	International Centre for Trade and Sustainable Development)
IRRs	Intellectual Property Rights
MEAs	Multilateral Environmental Agreements
miRNA	microRNA
NIH	National Institutes of Health
PCT	Patent Cooperation Treaty
PD	Parkinson's disease
PLT	Patent Law Treaty
RNA	Ribonucleic acid
RNAi	RNA interference
siRNA	Short interfering ribonucleic acid
SMA	Spinal muscular atrophy
SNP	Single nucleotide polymorphism
SPLT	Substantive Patent Law Treaty
TFEU	Treaty on the Functioning of the European Union
TRIPS	Trade Related Aspects of Intellectual Property Rights
UN	United Nations
UNEP	United Nations Environment Programme
UPOV	Convention for the Protection of New Varieties of Plants
USPTO	US Patent and Trademark Office
WHO	World Health Organisation
WIPO	World Intellectual Property Organisation
WTO	World Trade Organisation