

**BLOCK ME NOT: ARE PATENTED GENES 'ESSENTIAL
FACILITIES'?**

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ABSTRACT

The biopharmaceutical industry is characterized by the 'cumulative innovation' paradigm, wherein the discovery of a gene sequence is only the first step. In order to convert such sequence information into viable products, tests and cures for genetic conditions and diseases, vast amounts of additional time, effort and money have to be spent. It is feared that patents over upstream gene sequences may 'block' further downstream research and consequently adversely impact drug discovery, as many diseases today are known to have genetic origins.

This 'blocking' or 'restricted access' issue has been the subject of several important papers and a wide array of solutions have been suggested. However not many authors have suggested looking to the 'doctrine of essential facilities' as a potential solution. This doctrine stipulates that in certain circumstances, a monopolist in control of an 'essential facility' (gene sequences) can be ordered to grant access to its facility to others who may then go on to identify useful products/services.

Even amongst the few authors that have suggested an application of this doctrine, the treatment has been sparse—none of them have focussed on the most fundamental aspect of this doctrine, namely the concept of 'essentiality' or 'indispensability'. Consequently, this paper seeks to fill this gap by asking: 'how essential is a patented gene?' The paper will demonstrate that although it is difficult to invent around patented genes, it is not impossible-viable substitutes

do exist. To this extent, not all patented genes would qualify as 'essential' for the purposes of the application of the essential facilities doctrine.

The paper concludes by noting that an antitrust remedy cannot be a panacea to resolve the blocking or restricted access issue for all time to come. Rather, if the blocking issue becomes pervasive, it may be more prudent to devise a more focussed remedy.

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CHAPTER I

INTRODUCTION

The journey of a thousand miles begins with a single step—Lao Zi

The biopharmaceutical¹ industry is characterized by the 'cumulative innovation' paradigm, wherein the discovery of a gene² sequence is only the first step. In order to convert such sequence information into viable products, tests and cures for genetic conditions and diseases, vast amounts of additional time, effort and money have to be spent.³ It is feared that patents over upstream gene sequences may 'block' further downstream research and consequently adversely impact drug discovery, as many diseases today are known to have genetic origins.

¹ A 'biopharmaceutical' is defined broadly as 'any biology-based therapeutic that structurally mimics compounds found within the body': PC Nagle, TF Lugo and CA Nicita 'Defining and characterizing the late-stage biopharmaceutical pipeline' (2003) 9 (6) Am J Management Care 124. Biopharmaceuticals would therefore include recombinant proteins, monoclonal and polyclonal antibodies, peptides, antisense oligonucleotides, therapeutic genes, and certain therapeutic vaccines. However, in this paper, I use this term primarily in relation to 'therapeutic genes' and their resulting products.

² A gene refers to the 'basic physical and functional unit of heredity that is transmitted from one generation to the next and can be transcribed into a polypeptide or protein': D Suzuki and P Knudtson *Genethics* (Harvard Univ Press Harvard 1990) 343.

³ Jean Lanjouw describes the cumulative nature of the innovation process thus: 'The simplest model considers a two-staged research process, where the first stage is discovery and purification of a gene and the second stage is the development of a product based on that gene': JO Lanjouw 'A Discussion of "Of Patents and Genes: Flows of Knowledge and Intellectual Property Rights" by Claude Henry' (paper presented at the Annual Bank Conference on Development Economics [World Bank] May 2003) <[http://wbln0018.worldbank.org/eurvp/web.nsf/Pages/Paper+by+Lanjouw/\\$File/LANJOUW.PDF](http://wbln0018.worldbank.org/eurvp/web.nsf/Pages/Paper+by+Lanjouw/$File/LANJOUW.PDF)> (12 September 2004) 3.

My journey began as an earnest attempt to find an effective solution to the blocking impasse referred to above. Within a few miles of this endeavour, realisation struck that the journey was beset with multiple pathways and that not even one of them could be successfully traversed within the course of one paper. Caught at the crossroads of these daunting multiple pathways, I decided to plunge into what I thought would be the most promising pathway and ventured to take that single step.

A THE JOURNEY BEGINS: AN EXPLANATION OF THE TITLE

To begin with, an explanation of the title is in order. The phrase 'Block Me Not' is a play on the name of a highly sensitive plant, the 'Touch Me Not'. Known scientifically as *Mimosa Pudica*, this plant, found mainly in some Pacific islands, shrinks and withdraws into itself upon any kind of touch—hence the name. In much the same way as this plant, 'gene patents' are a highly sensitive issue and unless handled with appropriate delicacy, could have fatal ramifications for biomedical drug discovery. In this regard, it bears noting that this paper will focus largely on patents covering 'therapeutic genes'—the reason being that the cumulative structure of the biopharmaceutical industry is more pronounced in this context.⁴

The change from 'touch' to 'block' in the title is reflective of the 'blocking' problems inherent in the biopharmaceutical industry. It is important to clarify here that the term 'blocking' is used in a wide sense in this paper to include not only 'blocking patents',⁵ but also all instances where downstream research is

⁴ With a therapeutic gene, the chances of a further downstream product materializing are greater.

⁵ The term 'blocking patents' has a specific legal connotation in the United States, where it refers to 'blocking' in the context of dominant and subservient (dependent) patents—in order to move forward, the holder of the subservient patent requires a licence from the holder of the dominant patent, and vice versa. See RP Merges 'Intellectual Property Rights and Bargaining Breakdown: The Case of Blocking Patents' (1994) 62 Tenn L Rev 75.

blocked by patents on upstream inventions.⁶ A paper by Professor Walsh and others refers to this as the 'restricted access' issue.⁷ I will therefore, for the sake of convenience, refer to this phenomenon as the 'blocking' or 'restricted access' issue.

This 'blocking' or 'restricted access' issue has been the subject of several important papers⁸ and a wide array of solutions have been suggested, ranging from remedies within patent law (e.g. compulsory licensing of the patent, a wider research exemption etc) to remedies in other legal disciplines such as competition law or antitrust law.⁹ Amongst the various solutions proposed, the doctrine of essential facilities under competition law is particularly attractive and merits some detailed consideration. At its very core, an optimal resolution of the 'blocking' or 'restricted access' issue involves a balance between the granting of

⁶ See OB Arewa 'Blocking, Tackling and Holding: Boundaries, Marking and Strategic Business Uses of Intangibles' (Working Paper No 4 Case Research Paper Series September 2004) <<http://ssrn.com/abstract=586483>> (2 November 2004) who uses this term to refer broadly to include 'offensive and defensive strategic behaviors intended to block competitive technologies or competitors themselves, which may or may not have anything to do with the development of a commercial product based upon an intellectual property right such as a patent'.

⁷ J Walsh, A Arora and W Cohen 'Effects of Research Tool Patenting and Licensing on Biomedical Innovation' in WM Cohen and SA Merrill (eds) *Patents in the Knowledge-Based Economy* (National Academies Press Washington 2003) 287 (hereafter 'Walsh et al').

⁸ Professor Merges has dealt with the 'blocking' issue in some of his papers. See Merges (n 5). See also RP Merges and RR Nelson 'On the Complex Economics of Patent Scope' 90 Columbia LR 4 (1990) 839. However for a more specific reference to 'blocking' in the context of biotechnology or biopharmaceuticals, see 'Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies' (OECD Berlin 2002) 78 <<http://www.oecd.org/dataoecd/42/21/2491084.pdf>> (20 November 2004) (hereafter 'OECD Report'). See also Walsh et al (n 7), the jurisdictional focus of which is the United States. For a greater focus on the UK position, see the Nuffield Council on Bioethics 'The Ethics of Patenting DNA: A Discussion Paper' (Nuffield Council on Bioethics London) <<http://www.nuffieldbioethics.org/patentingdna/index.asp>> (18 November 2004) (hereafter 'Nuffield Paper'). For an empirical study of these issues in the Australian context, see D Nicol and J Nielsen 'Patents and Medical Biotechnology: An Empirical Analysis Of Issues Facing The Australian Industry' (Occasional Paper No. 6 Centre for Law and Genetics 2003) <<http://www.law.unimelb.edu.au/ipria/publications/workingpapers/BiotechReportFinal.pdf>> (5 November 2004) (hereafter 'Nicol and Nielsen'). Similarly, for an empirical study in this regard in the German context, see J Straus, H Holzapfel and M Lindenmeir 'Genetic Inventions and Patent Law'—An Empirical Survey of Selected German R & D Institutions' (Max Planck Institute for Intellectual Property, Competition and Tax Law, Munich 2004) copy on file with author (hereafter 'Straus et al').

⁹ The term 'antitrust law' is more specific to the US; Europe refers to this stream of law as 'competition law'. These terms will however be used interchangeably throughout this paper.

sufficient incentives to the upstream inventor, while at the same time ensuring that the patent rights granted are not broad enough to unduly block further downstream research.¹⁰ It would appear that a competition authority is particularly well placed for this task, given that it involves a significant amount of economic analysis.

B THE ESSENTIAL FACILITIES DOCTRINE

There is no standard definition for the term 'essential facilities doctrine'. Advocate General (AG) Jacobs in *Bronner*, however, captures its essence thus:¹¹

[A] company which has a dominant position in the provision of facilities which are essential for the supply of goods or services on another market abuses its dominant position where, without objective justification, it refuses access to those facilities. Thus in certain cases a dominant undertaking must not merely refrain from anti-competitive action but must actively promote competition by allowing potential competitors access to the facilities which it has developed.

Thus, for example, this doctrine would specify when a railroad must be made available on 'reasonable' terms to a rival rail company or a patented technology licensed to a competitor. In the specific context of a patented gene that blocks downstream research, a potential solution would lie in qualifying such gene as an 'essential facility', to which access has to be granted, in terms of licensing it

¹⁰ See Merges and Nelson (n 8), Rai (n 8) and Walsh (n 7). See also JH Barton 'Patents and Antitrust: A rethinking in the light of patent breadth and sequential innovation' (1997) 65 Antitrust LJ 44.

¹¹ Case C-7/97 *Oscar Bronner v Media Print GmbH* [1998] ECR I-7791 (AG opinion) [34] (hereafter 'Bronner (AG)'). The European courts are yet to make an explicit reference to the term 'essential facilities doctrine'. A number of their decisions dealing with 'refusals to deal' by a dominant company capture the essence of this doctrine. I will therefore use the term 'essential facilities doctrine' as a label to refer broadly to the central theme underlying this range of 'refusal to deal' decisions. See text to n 113.

on reasonable license terms to downstream researchers who could then go on to identify a useful product based on the gene.

However not many authors have suggested looking to the doctrine of essential facilities as a potential solution. Even amongst the few that have done so, the treatment has been sparse.¹² More specifically, none of them have focussed on the most fundamental aspect of this doctrine, namely the concept of 'essentiality' or 'indispensability'.¹³ Consequently, this paper seeks to fill this gap by asking: 'how essential is a patented gene?' In this sense, while the first part of the title ('Block Me Not') expresses the 'blocking' concern in general (the 1000 mile journey), the latter half ('Are patented genes essential facilities?') is the more specific question that this paper seeks to address (the first step in this long and arduous journey).

An important caveat—this paper does not offer a ready solution to the above conundrum of whether a patented gene is an essential facility (if at all it were possible to offer such a solution). It seeks a more modest role in attempting to map out a framework within which the above question can be answered on a case-by-case basis. Whilst working out the contours of this framework, I will cast some doubt on the oft-repeated view that it is impossible to 'invent' around a patented gene or to find a substitute for the same.

C STRUCTURE OF PAPER

In terms of the structure of this paper:

¹² See for example, Professor Westin who deals summarily with this doctrine: 'This doctrine could extend to genetic patent owners by analogizing genetic information as essential to the practice of all products stemming from the use of the genetic sequence': LB Westin 'Genetic Patents: Gatekeeper To The Promised Cures' (2002) 25 Thomas Jefferson L Rev 271, 293.

¹³ In fact, even authors who seek to analyse the essential facilities doctrine in relation to intellectual property generally (and not with specific reference to patented genes) do not pay sufficient attention to the 'essentiality' or 'indispensability' limb.

1. The first chapter introduces the 'blocking' or 'restricted access' issue, as thought to be prevalent in the biopharmaceutical arena (using the breast cancer gene (BRCA1 and 2) and the HIV gene (CCR5) controversies as specific examples). I will however caution that before we begin exploring remedies to this problem, we need to ask ourselves if there is any 'blocking' or 'restricted access' issue in the first place.
2. The second chapter engages in a brief comparative analysis of the primary antitrust remedy (the doctrine of essential facilities) in relation to the various internal remedies within patent law. This analysis merits some consideration owing to the fact that it seems counterintuitive to resort to competition law when supposedly good internal mechanisms lie within patent law to resolve this issue.
3. The third chapter explores the contours of the 'essential facilities doctrine' as drawn out by the European Commission/Courts and its application to intellectual property. I will specifically focus on the concept of 'essentiality' or 'indispensability' as elucidated in the various decisions and attempt to draw out a framework for assessing this limb.
4. In the fourth chapter, I will apply this framework to gene patents in order to assess their 'essentiality'. In particular, I will explore the viability of various alternatives to patented 'genes' and in the process cast doubt on the widely held assumption that patented genes cannot be invented around.
5. I will then conclude, drawing on the key points stressed in the earlier chapters.

D JURISDICTION

The thrust of the above examination will be under European/UK competition law. However, in so far as the paper undertakes a substantial assessment of patent law concepts, the jurisdictional focus will be UK law. As one would appreciate, this stems from the lack of a pan European patent law, at least in the sense in which there is a pan-European competition law stemming from the European Community Treaty 1957 (Treaty of Rome).¹⁴ However even in the context of patents, where possible, I will attempt to derive a broad European position, drawing from instruments such as the European Patent Convention, 1973 (hereafter 'EPC') and the Community Patent Convention, 1975 (hereafter 'CPC').

In the course of the discussion, other legal systems will be referenced, in particular, the law of the United States. The reason is simple enough—a highly litigious culture combined with a technologically sophisticated economy ensures that high technology cases tend to rear their heads first in this jurisdiction before finding their way to the others. Consequently, the chapter dealing with the 'essentiality' of a patented gene will, to the extent that is necessary to draw a comparative analysis, discuss US case law as well.¹⁵

CHAPTER II

GENE PATENTS: THE 'BLOCKING' OR 'RESTRICTED ACCESS' ISSUE

If it ain't broke, don't fix it.

¹⁴ Hereafter 'EC Treaty'.

¹⁵ Chapter V.

As mentioned earlier, the prospect of downstream inventions being 'blocked' by broad upstream patents¹⁶ is not merely anecdotal but has some historical basis. In a path-breaking paper, Merges and Nelson demonstrated that, in a variety of industries, broad upstream patents hindered further development of the technology.¹⁷ Thus for example, in the field of incandescent lighting, Thomas Edison's broad patent was used to shut down competitors with improvements.¹⁸

A BLOCKING IN THE BIOPHARMACEUTICAL INDUSTRY

The biopharmaceutical industry seems an ideal target for blocking problems to occur, given the fact that:

- i) Patents were granted at the initial stages of gene sequencing to DNA sequences, with no known function than their mere use as probes.¹⁹ Quite apart from the fact that these grants were not viewed as 'fair' ones,²⁰ inherent in these grants was the potential for blocking any

¹⁶ Professor Rai uses the terms 'upstream' and 'downstream' to 'identify the proximity (temporal and conceptual) of particular research to a particular end product'. She emphasizes however that these classifications are quite fluid. Thus, for example, 'research identifying a gene linked to a disease might be quite "upstream" if the commercial goal is a drug therapy. By contrast, if the commercial goal is a diagnostic test, research identifying the gene might be relatively "downstream"'. See AK Rai 'Fostering Cumulative Innovation in the Biopharmaceutical industry: The Role of Patents and Antitrust' (2001) 16 Berkeley Tech LJ 813, 816.

¹⁷ Merges and Nelson (n 8).

¹⁸ 'More importantly for our purposes, the validation of Edison's broad patent slowed down the pace of improvements considerably'. *ibid* 886.

¹⁹ S Basheer 'Patenting Genes And Gene Sequences: The Next El Dorado' Electronic Database of Intellectual Property (EDIP) Oxford (2002) 16 <users.ox.ac.uk/~edip/student_index.htm> (17 December 2004) 16.

²⁰ Professor Lanjouw states: 'One theme that runs through commentary on gene patents is a view that the "deal" in this case is not fair – that the rewards being reaped by those obtaining gene patents greatly exceed the amount they have invested': Lanjouw (n 3) 6. There is a tendency to treat the 'blocking' issue in tandem with the 'fairness' issue. The immediate focus of this paper however will be on remedying a 'blocking' situation, without delving into the issue of whether the patents that block are 'fair' ones or not. It may be the case that the 'fairness' or 'unfairness' could influence the outcome while applying the competition law remedy that is advocated in this paper—however time and space constraints compel me to omit that discussion.

further research using these patented sequences. To appreciate the magnitude of this issue, consider the fact that the total number of patents on genes and genetic material granted by the United States Patent and Trademark Office (USPTO) alone (up until the year 2002) was estimated to be around 8000—of which about 1500 covered human genetic material.²¹ Similarly, in the year 2000, about 605 patent applications pertaining to human or animal DNA sequences were filed at the European Patent Office (EPO).²²

- ii) Genes are finite in number.²³ Also, when compared with other inventions, it is extremely difficult to invent around patented genes or to find substitutes for the same.²⁴ Because of these factors, gene patents grant real monopolistic power in a market already fraught with inefficiencies.²⁵

- iii) A single gene may have more than one function. For example, mutations in the RET (Rearranged during Transfection) gene are responsible for two different disorders, Multiple Endocrine Neoplasia,

²¹ L Rivers (2002) Statement of Representative Lynn Rivers on the Introduction of the *Genomic Science and Technology Innovation Act of 2002*, and the *Genomic Research and Diagnostic Accessibility Act of 2002* to the US House of Representatives <http://www.house.gov/science_democrats/member/lr031402.htm> (14 December 2004). See also OECD Report (n 8) 34.

²² OECD Report (n 8) 8.

²³ During the early 1990's, when the patenting frenzy was beginning to catch on, it was thought that the human genome contained about 80,000 to 90,000 genes; recent research has however slashed this figure down to a mere 20,000 to 25,000 genes. See A Coghlan 'Recount slashes number of human genes' <<http://www.newscientist.com/news/news.jsp?id=ns99996561>> (26 December 2004). To this extent, it is important to note that this science is a relatively nascent and uncertain one.

²⁴ See Matthijs (n 175) 1359 and LB Andrews (n 55) 78-79. See also LB Westin (n 12) 297 who states 'However, unlike industry standards patents, whose technology may be performed in other ways, there is no substitute for the use of genes or genetic material when developing new drugs, therapies and diagnostic tools that are based on the genetic information'.

²⁵ Statement of JF Merz 'Oversight Hearing on Gene Patents and Other Genomic Inventions' The Subcommittee on Courts and Intellectual Property (US House of Representatives 13 July 2000) <<http://www.house.gov/judiciary/merz0713.htm>> (5 October 2004).

which includes thyroid cancer and Hirschsprung disease, a disorder of the intestinal tract. A single patent over the sequence would give the patent holder potential control over two very different disorders.²⁶ Most patent regimes stipulate that a patent over a novel product entitles the patentee to not only the use identified in the patent application but to all its uses, even those that that may be discovered in future by third parties.²⁷

Multiple patents over such gene sequences could also result in what Heller and Eisenberg refer to as the 'tragedy of the anti-commons'—a situation where there are numerous property right claims over the building blocks necessary for research and development.²⁸ If property rights over such building blocks are held by multiple owners, the negotiations necessary to bring these blocks together can fail, thus stifling follow-on innovations. In contrast to this prospect of an anti-commons, the 'blocking' or 'restricted access' issue is not a problem of accessing multiple patents but one of accessing relatively few patents—or perhaps even one patent on a key upstream invention.²⁹ Needless to state, the focus of this paper will be on the 'blocking' or 'restricted access' issue.

²⁶ WR Cornish et al 'Intellectual Property Rights (IPRs) and Genetics: A Study into the Impact and Management of Intellectual Property Rights within the Healthcare Sector' (Public Health Genetics Unit (PHGU) Cambridge 2003) 33 <www.phgu.org.uk> (10 September 2004).

²⁷ As the Nuffield Paper (n 8) 65 rightly notes: While it may be thought that the inventor's contribution does not deserve a monopoly over the compound *per se*, which covers all uses, the law provides for this because the inventor has provided the compound itself for others to work on.

²⁸ MA Heller and RS Eisenberg 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280 Science 698.

²⁹ Interestingly, in a later paper, co-authored with Professor Rai, Professor Eisenberg states: 'It bears mention that the problems of unduly broad patent scope and proliferation of patent rights held by multiple owners can occur simultaneously. An initial broad patent on a pioneering research discovery doesn't necessarily preclude a proliferation of upstream patents related to that discovery. To the contrary, follow-on improvers often seek and obtain patent rights within the scope of the claims of the initial broad patent': RS Eisenberg and AK Rai 'The Public Domain: Bayh-Dole Reform and the Progress of Biomedicine' (2003) 66 Law and Contemporary Problems 289.

Illustratively, two of the most controversial gene patents that have raised concerns of blocking in a stark manner and therefore deserve discussion are patents covering the CCR5 gene and the BRCA genes.

1 CCR5 Patent

In 2000, the USPTO granted a patent to Human Genome Sciences Inc (HGS) covering the gene sequence of the CCR5 receptor.³⁰ This receptor is a protein³¹ that plays a central role in the mechanism by which human immunodeficiency virus (HIV) binds to and enters white blood cells, and therefore represents a key target in the search for effective novel treatments for HIV infection and AIDS.³² However, in the HGS patent application, a utility in HIV research was not mentioned.³³ Rather, the utility of the invention was defined, among other things, as a tool for screening for receptor agonists and antagonists, and as a diagnostic tool for detecting mutations in the gene itself.³⁴

Other researchers, such as Professor Marc Parmentier, subsequently discovered that the CCR5 receptor was the 'docking receptor' used by the HIV virus to

³⁰ US Patent No. 6,025,154 (2000).

³¹ A protein is a molecule composed of interacting polypeptides (chains of three or more amino acids joined together) that are folded or twisted into characteristic shapes. Proteins serve essential functions in the human body. Illustratively, they regulate metabolism (enzymes), make up skin, bones, and ligaments (keratin and collagen), produce movements (muscle proteins), transport oxygen (haemoglobin) and regulate movement into and out of cells (membrane proteins). See *Hutchinson Dictionary Of Science* (Brockhampton Press Ltd 1997) 265.

³² NL Michael et al 'The Role of CCR5 and CCR2 Polymorphisms in HIV-1 Transmission and Disease Progression' (1997) 3 *Nature Medicine* 1160.

³³ E Marshall 'Patent On HIV Receptor Provokes An Outcry' (2000) 287 *Science* 1375.

³⁴ HGS filed its patent application for the CCR5 gene as a so-called 'homologous sequence' i.e. a gene sequence of unknown utility whose biological function could be predicted because it was similar to a separate sequence whose function had already been identified. This process of identification was fairly routine in the industry. See D Dickson 'NIH Opposes Plans for Patenting 'Similar' Gene Sequences' (2000) 405 *Nature* 3. See also M Enserink 'Patent Office May Raise the Bar on Gene Claims' (2000) 287 *Science* 1196, 1197.

infect a cell.³⁵ HGS's patent meant that such researchers could be excluded or 'blocked' from using the CCR5 gene in their research. Fortunately however, this prospect of 'blocking' never fructified, owing in large part to HGS's immediate commitment to license the CCR5 patent on reasonable terms.³⁶ The main reason underlying this commitment appears to be the fact that the public decried the grant of this patent when the utility cited by HGS was highly speculative and HGS had no idea of the nexus between the CCR5 receptor and HIV infection.

2 BRCA Patents

In another controversial case, Myriad Genetics (a US corporation) was accused of stifling research by demanding excessive royalties in respect of its patents covering the breast cancer genes, BRCA1 and 2.³⁷ It was feared that Myriad's actions would prevent the emergence of new and improved tests for diagnosing breast cancer.³⁸ This fear became even more real when researchers at the Institut Curie, a French research institute used one of their technologies, called 'combed DNA colour bar coding' to identify a mutation in BRCA1 in a patient who had received a negative result (no mutations detected) when tested by Myriad.³⁹ This indicated that Myriad's tests were far from perfect and that their

³⁵ A patent was recently granted in this regard to 'Euroscreen', a Belgian company, of which Parmentier is the founder. See 'Euroscreen awarded US patent covering key HIV target' Patent Café International (12 September 2002) <http://www.cafezine.com/index_article.asp?deptId=6&id=619&page=1> (4 October 2004).

³⁶ Marshall (n 33).

³⁷ Myriad currently holds approximately twenty patents worldwide covering the BRCA1 and BRCA2 genes, certain mutations of the genes and tests to detect mutations in these genes. See J Paradise 'European Opposition To Exclusive Control Over Predictive Breast Cancer Testing And The Inherent Implications For US Patent Law And Public Policy: A Case Study Of The Myriad Genetics' BRCA Patent Controversy' (2004) 59 (1) Food and Drug LJ 133, 136.

³⁸ Myriad's screening method aims to detect mutations in the breast cancer genes. Such mutations are thought to render a person more susceptible to breast cancer. See SJR Bostyn 'The Prodigal Son: The Relationship between Patent Law and Health Care' (2003) 11(1) Medical LR 67, 106.

³⁹ BW Jones 'History of a Gene Patent: Tracing the Development and Application of commercial BRCA Testing' (2002) 10 Health LJ 123, 139.

approach to testing (which involved full DNA sequencing of the two BRCA genes) could only detect small-scale deletions and re-arrangements. Myriad's patents however ensured that it could stunt the emergence of any such tests.⁴⁰

Here again, as with the CCR5 experience, a variety of factors ensured that the 'blocking' or 'restricted access' threat was mitigated. For one, with the recent grant of a European patent covering the BRCA 2 gene to an English charity (Cancer Research (UK)), the impact of Myriad's monopoly over the breast cancer genes stand diminished.⁴¹ This charity has committed to granting royalty free licences to public laboratories throughout Europe.

More recently, following an opposition hearing launched by several European scientific institutes, one of Myriad's patents over the BRCA1 gene was invalidated by the European Patent Office (hereafter EPO) on grounds of lack of novelty.⁴² This development reduces the impact of Myriad's monopoly even further.

B 'WALSH ET AL' PAPER AND 'WORKING SOLUTIONS'

The fact that 'blocking' concerns in the above cases were mitigated to some extent (by external circumstances, or as was the case with CCR5, the parties'

⁴⁰ The lab of a geneticist at the University of Pennsylvania, Arupa Ganguly, was stopped from testing, despite the fact that the tests were believed to be more accurate and cheaper than that of Myriad and the fact that some of the testing was done for research purposes. See J Borger 'Rush to Patent Genes Stalls Cures for Disease' <<http://www.guardian.co.uk/Archive/Article/0,4273,3941983,00.html>> (26 December 2004).

⁴¹ The patent covers all attempts to sequence the gene or to test for damaged and inactive variants. See S Mayor 'Charity Wins BRCA2 Patent: Genetics Researchers Welcome a Decision That Will Make the Gene Freely Available in Europe' <<http://www.biomedcentral.com/news/20040213/02>> (28 September 2004).

⁴² The patent covered methods to predict a woman's predisposition to develop breast or ovarian cancer by looking at certain mutations in the BRCA1 gene. See S Bodoni 'EPO Revokes Myriad Cancer Test Patent' Managing Intellectual Property (MIP) <<http://www.legalmediagroup.com>> (6 December 2004).

own conduct) does lead one to speculate that is some disconnect between the perceived fears of blocking and their actual translation into practice. This was the central theme of a recent paper by Professor John Walsh and others,⁴³ where they demonstrated that the theoretical possibility of 'blocking' concerns echoed by many scholars may have been offset by certain 'working solutions' adopted by the industry.

These 'working solutions' include the taking of licences, inventing around patents, infringement (often informally invoking a research exemption), going offshore, developing and using public tools, and challenging patents in court.⁴⁴

The conclusions of the Walsh et al paper were broadly reflected in an OECD report as well which stated:

The few examples used to illustrate theoretical economic and legal concerns related to the potential for the over-fragmentation of patent rights, blocking patents, uncertainty due to dependency and abusive monopoly positions appear anecdotal and are not supported by existing economic studies.⁴⁵

This forces us to revisit an assumption that this paper is based upon: Is there a 'blocking' or 'restricted access' concern in the first place? Surely, if there is none, we do not need to look for remedies or ways of tackling it.

⁴³ Walsh et al (n 7). This paper dealt with whether the prospect of an 'anticommons' as feared by Heller and Eisenberg had been realized and also whether the restrictions on access to upstream discoveries impeded biomedical innovation. As noted earlier, the 'anticommons issue' is quite distinct from the 'blocking' or the 'restricted access' issue and my focus will be on the latter.

⁴⁴ *ibid* 286.

⁴⁵ *OECD Report* (n 8). This report stemmed out of a workshop (held by the OECD Working Party on Biotechnology on 24-25 January 2002), in which several experts, including Dr Straus and Dr Walsh presented their findings.

It is important to note here that Walsh et al cautioned that notwithstanding the 'working solutions' referred to by them, access tended to be an issue when a research tool was 'rival-in-use' and was potentially key to progress in one or more broad therapeutic areas.⁴⁶ They cited the example of a patent over human embryonic stem cell technology owned by the Wisconsin Alumni Research Foundation's (WARF) and exclusively licensed to Geron, a private biotechnology firm, to demonstrate how restrictions on access to an important, broadly useful technology could potentially retard its development.⁴⁷

The scope of the patent, the fact that the patent was a 'pioneer' patent, and the federal funding limitations laid down by the Bush Administration greatly increased the fear that such 'exclusive licenses on research tools with potentially broad applications threaten to throttle scientific progress by limiting the number of players in a developing field.'⁴⁸

In order to prevent Geron from expanding its rights to include an additional 12 tissue types and in order to be able to offer licensing rights to Geron's competitors, WARF went to court in August 2001. This suit was settled in January 2002, with the settlement effectively narrowing Geron's exclusive commercial rights to the development of only three types of cells—neural, heart, and pancreatic. Geron and WARF also agreed to grant royalty free licences to

⁴⁶ Walsh et al (n 7) 333. See also JP Walsh, A Arora and WM Cohen 'Working through the Patent Problem' (2003) 299 Science 1021.

⁴⁷ Owing to a moratorium on federal funding for research on human embryonic stem cells, research by the University of Wisconsin on human stem cells that finally led up to the patent (covering primate embryonic stem cell lines) was funded by Geron and not by the Federal Government. Geron agreed to provide funding in exchange for exclusive rights to develop human stem cells into six tissue types that might be used to treat disease as well as options to acquire the exclusive rights to others. See Walsh et al (n 7) 308.

⁴⁸ Eisenberg and Rai (n 29) 301.

academic and government scientists to use the stem cell patents for purely 'research' purposes.

Despite this settlement, the fact that Geron still retained control over key application areas of the technology⁴⁹ was cause for concern—there were indications that it wished to pursue those applications itself to the exclusion of others.⁵⁰ Similarly, although it agreed to freely license the stem cell patent rights for research-only uses, there still remained the possibility of stifling innovation—as some researchers would not have wanted to embark upon research that could not, at a later stage, be effectively commercialised by them.

Walsh et al therefore warned that there could be 'future problems resulting from patents currently under review, court decisions, new shifts in technology, or even assertions of patents on foundational discoveries' and anticipated 'a continuing need for the active defense of open science.'⁵¹

Notwithstanding the paper itself cautioning that its findings may not hold true for all time to come, some of the findings in the paper have met with skepticism. In relation to the 'working solution' that was premised on private firms simply ignoring research tool patents and hoping that difficulties in detecting infringement would fend off law suits,⁵² Professors Rai and Eisenberg rightly note:

⁴⁹ CR Carroll 'Selling the Stem Cell: The Licensing of the Stem Cell Patent and Possible Antitrust Consequences' (2002) U Illinois J L Technology and Policy 435, 447–48.

⁵⁰ This is made evident by the statement of David Greenwood (CFO and senior VP of Geron), who noted that Geron did not have to allow others to develop products in the three areas where it retained exclusive rights. See Walsh et al (n 7) 309.

⁵¹ Walsh et al (n 7) 335.

⁵² See n 44. See also Walsh et al (n 7) 324-28.

Although the study characterizes this firm behaviour as a 'working solution', one might question the long-term viability of a solution that is based on pervasive law-breaking that may yet trigger costly litigation when it comes to light.⁵³

One cannot therefore expect the repertoire of 'working solutions' to provide a lasting solution to the blocking or 'restricted access' concern. The proliferation of incidents such as those involving Myriad and Geron could inflict significant social costs. The licensing practices of the owners of patents for other genetic tests—for example, Athena's Alzheimer's (ApoE) test, and the test owned by Miami Children's Hospital for Canavan's disease—have also raised concern about high costs and limited access to genetic tests.⁵⁴ One needs therefore to think of effective solutions to redress the blocking impasse.

C PROPOSED SOLUTIONS FOR THE BLOCKING IMPASSE

A variety of solutions, mostly centred around patent law, have been proposed to tackle the blocking issue.⁵⁵ Some recommend a more effective use of existing patent doctrine while others insist on patent law reform. A few of these proposals are:

⁵³ Eisenberg and Rai (n 29) 318.

⁵⁴ A 1999 survey of the licensing practices of holders of patents that covered the diagnosis of genetic disorders showed that almost all the patents were being licensed exclusively. See Schissel et al 'Survey Confirms Fears about Licensing of Genetic Tests' *Nature* (1999) 402 November 118. The OECD report also cautions that 'empirical studies have shown problems arising over access to diagnostic genetic tests, although the exact cause of these problems has not been fully elucidated'. See OECD Report (n 8) 77.

⁵⁵ See LB Andrews 'The Gene Patent Dilemma: Balancing Commercial Incentives with Health Needs', (2002) *Houston J Health L & Policy* 65, 66-67.

- i) Prohibiting gene patents altogether.⁵⁶
- ii) Ensuring that the patent monopoly on a gene sequence is limited to the specific function disclosed and not to all functions.⁵⁷
- iii) Automatically subjecting all gene patents to compulsory licences.⁵⁸

Some others have sought to redress these issues outside the confines of patent law, such as the application of competition law,⁵⁹ or even price regulation. Illustratively, Professor Bostyn proposes that '[i]f DNA patents lead to excessive prices of health care, then governments should take price measures instead of prohibiting patentability of DNA sequences'.⁶⁰

Of all the proposed solutions, the essential facilities doctrine within competition law appears the most promising and will consequently be the focus of this paper. Given time and space constraints, a comparative analysis of all the solutions proposed is beyond the scope of this paper. However, in so far as potential remedies exist within patent law to address the blocking impasse, I will attempt to demonstrate why these would be seen as deficient, when compared with an application of the essential facilities doctrine.

⁵⁶ Dr Carvahallo argues that the solution to problems posed by gene patents does not lie in diminishing patent rights, but rather in accepting that genes are non-patentable subject matter. See NP Carvalho 'The Problem of Gene Patents' (2004) 3 Washington U Global Stud L Rev 701, 702.

⁵⁷ See Nuffield Paper (n 8) 87. See also FM Scherer 'The Economics of Human Gene Patents' (2002) 77 Academic Medicine 1348. In fact, a biotechnology amendment approved on 3 December 2004 by Germany's Bundestag (lower house of Parliament) limits patent protection on human gene sequences to "disclosed functions" at the time of the patent application i.e a patent on a human DNA sequence used for a specific function would not cover a second function discovered later by another researcher using the same DNA sequence. See N Stafford 'German Biopatent Law Passed' <<http://www.biomedcentral.com/news/20041209/01>> (24 December 2004).

⁵⁸ See DM Gitter 'International Conflicts Over Patenting Human DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and a Fair-Use Exemption' (2003) 76 New York L Rev 1623.

⁵⁹ See Westin (n 12) 297 who recommends the application of the 'essential facilities doctrine'.

⁶⁰ See Bostyn (n 38) 120.

CHAPTER III

PATENT LAW REMEDIES VERSUS COMPETITION LAW REMEDY

*Mirror, Mirror, on the wall,
Who's the fairest one of all?*⁶¹

As mentioned in the last chapter, it is not my intention to do a comparative analysis of all the solutions proposed to remedy the 'blocking' impasse. Rather, my more limited quest will be in attempting to satisfy those guardians of patent law who are likely to query: 'Why turn to competition law at all? Are not remedies within patent law (hereafter 'internal remedies') adequate to resolve the blocking or 'restricted access' issue?'

I will strive to demonstrate in this chapter that the 'internal remedies' are not sufficient to cater to the 'blocking' dilemma. However prior to addressing this, another broader and more general issue arises: Does the existence of remedies within patent law pre-empt the application of competition law in the first place? Here again, the immediate answer is 'no'—I elaborate as below:

A PRE-EMPTION OF COMPETITION LAW?

In order to restore competition in the market, it would appear that under EC competition law, a competition authority has overarching powers to interfere, even where there is sector-specific legislation. In *Deutsche Telekom*,⁶² the court

⁶¹ *Snow White and the Seven Dwarfs* Translated and Illustrated by W Gag (Coward-McCann New York 1938) 10.

⁶² Commission Decision No. 2003/707/EC *Deutsche Telekom AG* OJ L 263 (14 October 2003) 9, 17.

endorsed previous rulings⁶³ that consistently held that competition rules would apply where the sector-specific legislation does not preclude the undertakings it governs from engaging in autonomous conduct that prevents, restricts or distorts competition.

Although intellectual property legislation is not on the same footing as telecommunications regulation or other sector specific legislation, the above logic could be transposed to intellectual property legislation as well. On the narrow principle postulated above, it is clear that since patent legislations confer sufficient autonomy on patentees to engage in conduct that could qualify as anticompetitive (attested to by a long line of cases involving anticompetitive conduct by patent holders), a competition authority has jurisdictional competence to intervene, despite the existence of patent legislation.

1 *Microsoft Decision*

The above does not squarely answer the more specific issue of whether a competition authority ought to intervene when the 'internal' remedies within patent law are adequate. Perhaps some guidance may be had from the recent *Microsoft* case, which touches peripherally on this issue.⁶⁴ The Commission had in this decision ordered Microsoft to supply interface information relating to its servers to other server (operating-system) vendors.

⁶³ *Commission and France v Ladbroke Racing* [1997] ECR I-6225 [34]; *Irish Sugar v Commission* [1999] ECR II-296 [130]; *Consiglio Nazionale degli Spedizionieri Doganali* [2000] ECR II-1807 [59]. The approach in the US is best reflected in a recent case where the Supreme Court concluded that unless there was a plain repugnancy—a clear clash between the intent of a sector-specific statute and antitrust law, they would not assume that a regulatory statute implicitly repeals the antitrust law.' See *Verizon Communications Inc v Curtis V Trinko LLP* 540 US 682 (2004) (hereafter 'Trinko').

⁶⁴ Commission Decision of 24 March 2004 (Case COMP/C-3/37 792 *Microsoft*) C (2004) 900 final.

In response to Microsoft's argument that such an order would upset the careful balance between copyright and competition policies struck by the Software Directive, the Commission stated categorically that 'it is important to first note that the law applied in this case is Article 82 of the Treaty and not the Software Directive'.⁶⁵ This statement, in and of itself, seems to suggest that an application of competition law would be independent of the existence of other legislations.⁶⁶ The Commission went on to point out that the Software Directive, being secondary Community legislation, could not, in any event, supersede Article 82.⁶⁷ This however begs the question: What if the Software Directive was not merely a Directive but was part of the EC Treaty, much like EC competition norms?

Most intellectual property norms considered by the Commission or the European courts, to date, have stemmed from either national legislation or EU Directives—clearly these would be subservient to competition rules found in the EC Treaty itself.⁶⁸ Therefore at this stage, the only serious limitation on a competition authority's power to intervene appears to be the presence of

⁶⁵ *ibid* [744].

⁶⁶ This takes us back to the more general issue of the relationship between intellectual property and competition law. However, I will deal with this issue only to the limited extent of addressing the key theme in this paper—would a patented gene qualify as an essential facility?

⁶⁷ Microsoft (n 64) [744]. The Commission further went on to state that the subservience of the Directive is also made evident by the fact that Recital 27 of the Directive states that the provisions of the Directive are '...without prejudice to the application of the competition rules under Articles 85 [now 81] and 86 [now 82] of the Treaty if a dominant supplier refuses to make information available which is necessary for interoperability as defined in [the] Directive'. *ibid* [748].

⁶⁸ It bears noting at this juncture that there is no pan-European intellectual property legislation in the same way that the EC Treaty carves out competition law principles (see text to n14). However there is considerable harmonization between national intellectual property regimes as a result of European legal instruments (mainly Directives). Thus, when faced with what seems like a pre-emption claim, the Commission often stresses the supremacy of EC competition law. For example, in the recent *IMS* case, when considering the impact of the Database Directive, the Commission noted in pertinent part that '...the application of a Treaty article takes precedence over a Directive...' See Commission Decision 2002/165 in Case COMP D3/38 044 *NDC Health/IMS Health: Interim measures* [2002] OJ L59/18 (hereafter '*IMS I*'). [205].

international treaties such as TRIPS⁶⁹ or the Berne Convention⁷⁰. The Berne Convention was called into question in *Magill*—the European Court of Justice (hereafter 'ECJ') however sidestepped the issue by ruling that the European Community was not a party to Berne.⁷¹

The Commission in *Microsoft* then interestingly seemed to suggest that one of the internal remedies within the Directive to promote inter-operability (the 'decompilation' defence) was 'passive' and was not sufficient to ensure competitiveness in this context. According to the Commission, its decision to mandate Microsoft to *actively* supply interface information to other server (operating-system) vendors, while being consistent with the Software Directive (as regards the balancing of intellectual property rights and interoperability), endorses a disclosure obligation under Article 82 of the Treaty which goes beyond 'mere passivity in the face of de-compilation of its software code for interoperability purposes'.⁷²

The Commission's decision to order disclosure under competition policy appears therefore to be based to some extent upon the inadequacy of 'internal remedies' to cater appropriately to the problem of access by Sun and other competitors of Microsoft. Had the remedy within the Directive been 'adequate', this may have been enough to dispose of the issue, since the 'facility' (Microsoft's code) would not then have been treated as an 'essential' one by the Commission. Even on the facts as they stand, this decision has been severely criticized as not adhering to the traditionally strict parameters of 'essentiality' spelt out in *Magill* and *IMS*—aspects that will be dealt with in greater detail in the next chapter. A

⁶⁹ Agreement on Trade-Related Aspects of Intellectual Property Rights (15 April 1994) LT/UR/A-1C/IP/1 (hereafter 'TRIPS').

⁷⁰ Berne Convention for the Protection of Literary and Artistic Works 1886 (Paris Act 24 July 1971) (hereafter 'Berne Convention').

⁷¹ Joined Cases C 241 & 242/91 P *RTE and ITP v. European Commission* [1995] ECR I-743, [1995] 4 CMLR 718 [83] (hereafter 'Magill').

⁷² *Microsoft* (n 64) [747].

commentator goes to the extent of claiming that the decision seems to have evolved a concept of 'convenient facilities' as opposed to 'essential facilities'. He states in pertinent part:

By requiring compulsory access to a facility without which it is inconvenient (rather than essential) for rivals to do business, the Commission has in effect declared an ability to micromanage competition in a way that goes well beyond the 'last resort' intervention that normally characterises compulsory access cases.⁷³

In this context, it needs to be noted that even in the absence of a general pre-emption doctrine, the existence of patent law remedies could nonetheless influence the outcome in a competition proceeding. Thus for example, the fact that a patent legislation specifies that patents could be 'compulsorily' licensed to remedy a 'blocking' situation ought to mean that the 'facility' itself is not an 'essential' one for the purposes of the application of the essential facilities doctrine. One needs therefore to investigate whether any of the existing patent law remedies are adequate enough to remedy a 'blocking' situation.

B REMEDIES WITHIN PATENT LAW

Amongst the various solutions within patent law that can potentially redress the blocking issue,⁷⁴ some of the most pertinent are:

⁷³ D Ridyard 'Compulsory Access under EC Competition Law—A New Doctrine of "Convenient Facilities" and the Case for Price Regulation' (2004) 25(11) ECLR 669.

⁷⁴ Some scholars have recommended patent law reform as a panacea to the 'blocking' problem. Some of the proposals include barring gene patents altogether, ensuring that rights be granted only with respect to specific functions identified and subjecting all gene patents automatically to compulsory licences. See n 56-58. However since the focus of this paper is the use of existing law/legal principles rather than law reform of any sort, such proposals will not be deliberated upon in any detail.

- i) Granting a compulsory license in respect of the patented gene to any downstream researcher;
- ii) Invoking the research exemption; and
- iii) A tightening of the patentability criteria and a rigorous examination procedure to limit the scope of a gene patent.

Of these, the compulsory licensing scheme within patent law is perhaps the closest parallel to the doctrine of essential facilities under competition law⁷⁵—a comparison in this regard will therefore be the primary focus of this discussion.

1 Compulsory Licensing in Patent Law

At the outset, it must be noted that there is no uniform law on compulsory licensing in Europe. As opposed to the EPC, the CPC does mention 'compulsory licensing'. However its provisions amount to nothing more than an attempt to reconcile compulsory licensing provisions pertaining to national patents (under respective national laws) with a 'community patent' regime. Thus, for example, it is provided that national law provisions for the grant of compulsory licences (in respect of national patents) would be applicable to 'community patents' as well.⁷⁶ In this part of the paper therefore, I have, much in line with my jurisdictional focus spelt out in the introduction, attempted to deal more with the English position than with a general pan-European position.

In terms of the 'compulsory licensing' provisions in the UK patent regime,⁷⁷ the main shortcomings when compared with the essential facilities doctrine are:

⁷⁵ The doctrine of 'patent misuse' is also relevant to this discussion. I do not engage with this, as this is primarily a US remedy, whereas my jurisdictional focus is EC law.

⁷⁶ Article 45 (CPC).

⁷⁷ The main statute regulating English patent law and practice since 1 June 1978 has been the Patents Act 1977 (as amended by the CDPA 1988) together with the Patent Rules, 1995 (made under the 1977 Act). The Act (hereafter 'UK Patents Act') is expressly intended to follow various

- i) The scope of the grounds upon which a compulsory licence can be granted are very limited and cannot appropriately cater to a 'blocking' impasse. In the words of a commentator:⁷⁸

Recourse to the 'essential facilities doctrine' must be distinguished from the grant of compulsory licence, which is usually limited by rather strict conditions, especially a related invention of the licensee and the dependency of its use on such licence. The 'essential facility concept' has a broad operation.

- ii) There have been very few instances of the compulsory licensing regime in the UK actually being invoked, owing, in large part, to the procedural difficulties associated with invoking this remedy.⁷⁹ A 1967 US government study speculated that the UK compulsory licensing provisions may have been used infrequently because of the cumbersome and time-consuming procedures involved, which among other things permitted compulsory licensing only after a patent had been in force for at least three years.⁸⁰ In contrast, the essential

international conventions including the EPC, CPC, TRIPS, PCT and the Paris Convention. Each European patent granted for the UK is to be treated as if it were a UK patent granted under the 1977 Act—this means *inter alia* that validity and infringement are determined nationally. See BC Reid (Gen Editor) *Sweet and Maxwell's European Patent Litigation Handbook* (Sweet and Maxwell London 1999).

⁷⁸ M Herdegen 'Patenting Human Genes and other Parts of the Human Body under EC Biotechnology Directive' (2001) 4(3) *Bioscience L Rev* 102, 106.

⁷⁹ D Perkins 'Compulsory Licensing in Europe' Impact of the Doha Public Health Declaration (ICC / AIPLA joint conference Paris 13 September 2002).

⁸⁰ 'US Department of Health, Education and Welfare' (1968) 177, cited from FM Scherer 'The Economics of Compulsory Drug Patent Licensing' <<http://www1.worldbank.org/hnp/hsd/documents/F.M.%20Schere%20-%20paper.pdf>> (30 November 2004).

facilities doctrine seems to be more widely applicable and is rapidly gaining momentum in Europe.

In terms of limitations in the scope of 'compulsory licensing' grounds available, it is helpful to have a look at the specific provisions within the UK patent regime. The main grounds spelt out in section 48A⁸¹ that are relevant for the purpose of this discussion are:

- i) A demand in the UK for the patented product is not being met on reasonable terms;
- ii) A refusal to license the patent on reasonable terms prevents or hinders the exploitation in the UK of any other patented invention which involves an important technical advance of considerable economic significance;
- iii) A refusal to license on reasonable terms unfairly prejudices the establishment or development of commercial or industrial activities in the UK.

None of the above grounds would cater appropriately to blocking concerns in the biopharmaceutical industry. As regards the first ground, it may be difficult to argue that a demand for the upstream genetic invention is not being met. Such 'invention' itself may be available in the market—however this availability does

⁸¹ The grounds in section 48A pertain to 'WTO patent' proprietors. In order to comply with TRIPS, UK patent law was amended in 1999 to distinguish between 'WTO patent' proprietors and 'non-WTO patent' proprietors when considering the applicable grounds for a compulsory licence. This difference is in large part influenced by Article 27 of TRIPS that bars the discrimination of patents on the basis of their being imported or worked in the UK. Thus, while the non-WTO applications could be subjected to a local working requirement (i.e. a compulsory licence could issue if the invention is not worked in the UK), the WTO applications cannot be so subjected. See S Thorley et al *Terrell on the Law of Patents* (15th edn Sweet and Maxwell London 2002) 341.

not necessarily mean that it is also being reasonably licensed to downstream researchers.

The second ground relates to what are known generally as 'blocking patents'⁸². The main limitation of this provision in addressing the blocking problem is that the downstream researcher requesting access to the upstream patent may not as yet hold a downstream patent.

Similarly, in respect of the third ground, it may be difficult to qualify all cases of blocking in the biopharmaceutical industry as preventing 'the establishment or development of commercial or industrial activities'.

Quite apart from these grounds, some countries provide for 'public health' as a separate 'compulsory licensing' ground. Thus, for example, French law authorizes compulsory licenses when medicines are 'only available to the public in insufficient quantity or quality or at abnormally high prices'.⁸³ More recently, France amended this provision to cater to a Myriad-like situation where the patentee charges unreasonably high prices for genetic diagnostic testing kits.⁸⁴ Indeed, TRIPS specifically provides that WTO Members may adopt measures necessary to promote 'public health', subject to such measures being consistent with TRIPS.⁸⁵ From this provision, as also the recent Doha declaration,⁸⁶ it would

⁸² See n 5.

⁸³ Article L 613-16 <<http://www.cptech.org/ip/health/cl/france1.html>> (20 October 2004).

⁸⁴ Article 18 of Loi n 2004-800 (6 August 2004) <www.legifrance.gouv.fr/WAspad/UnTexteDeJorf?numjo=SANX0100053L> (20 October 2004).

⁸⁵ Article 8 (1) of TRIPS. While the TRIPS framework does not contain extensive provisions on available grounds (member states are left to determine such grounds themselves), it is quite specific with respect to the conditions to be met should a compulsory license be granted. These conditions include, *inter alia* the requirement (in certain cases) that a license be voluntarily requested before being granted on compulsory terms, non-exclusivity, and an adequate remuneration to the patent holder. See Articles 8, 30 and 31.

⁸⁶ The fourth Ministerial Conference of the WTO issued a declaration in Doha (Qatar) in order to elucidate the TRIPS Agreement. The declaration stated in pertinent part that '...the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.' See 'Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (14 November

appear that TRIPS endorses a compulsory licensing ground based substantially on public health.

This ground may not however directly help in the context of a 'blocking' impasse as it assumes the existence of an immediate public health issue and the presence of (or immediate potential for) a product ready to address this. In the context of biopharmaceutical research using an upstream patented gene, a downstream product may not as yet be available—in fact, it may be several years away from coming into fruition. Further, not every blocking or restricted issue can be readily classified as a 'public health' issue.

2 Scope of the 'Research Exemption'

A 'research exemption' that permits downstream researchers to 'use' the patented gene sequence is another way of tackling the blocking impasse. However the scope of this exception is limited, rendering it an inappropriate tool for the context under discussion.

In the UK, the 'experimental use' exemption is codified under section 60(5)(b) of the UK Patents Act and covers in pertinent part, an act 'done for experimental purposes relating to the subject-matter of the invention'. Apart from *Monsanto v Stauffer*,⁸⁷ which indicates that the scope of this section is limited, there is not much case law to help assess the proper scope of this section. However going by the wordings of the statute, it appears that section 60(5)(b) has an important

2001) paragraph 4
<http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm> (22 September 2004).

⁸⁷ [1985] RPC 515. In the US, the exception is even more limited. *Whittemore v Cutter* 29 F Cas 1120 (CCD Mass 1813), perhaps the earliest case on this point, expressly limits the exception to acts conducted solely for the purpose of philosophical or scientific inquiry. This was reiterated in a recent case, *Madey v Duke* 307 F 3d 1351 (Fed Cir 2002), where the US Supreme Court shifted the focus of the experimental use defence from the 'commercial versus non-commercial' nature of the experimentation and the 'profit versus non-profit' status of the alleged infringer to merely a question of whether the use was in furtherance of the alleged infringer's legitimate business.

limitation—the ‘experimental use’ must ‘relate to the subject matter of the invention’. This could be interpreted to mean that the section appears to permit experimentation ‘on’, but not ‘with’, the invention.

This distinction becomes particularly relevant in the context of those gene patents that qualify as ‘research tools’. ‘Research tool’ patents constitute a rather unique genre of patents, in that their predominant utility is in research itself. If everyone were allowed to construct a research tool on their own, use it for further research, and successfully claim shelter under the ‘experimental use’ exemption, the grant of a patent to ‘research tools’ would become meaningless.⁸⁸ Consequently, a distinction between ‘experimenting on’, and ‘experimenting with’ prevents such patents from being rendered ineffective. However this would also mean that in the specific context of blocking, which requires a downstream researcher to work ‘with’ an invention, this exception is only of limited utility.⁸⁹

The research exemption is limited in another significant way: it may not permit the manufacture or sale of the downstream product, if such product or its manufacture incorporates/uses the patented gene sequence. Perhaps here, the compulsory licensing ground pertaining to ‘blocking patents’ could help, if the downstream product were covered by a patent as well.⁹⁰

⁸⁸ See J M Mueller ‘No “Dilettante Affair”: Rethinking The Experimental Use Exception To Patent Infringement for Biomedical Research Tools’ (2001) 76 Wash L Rev 1, 13.

⁸⁹ However, it is important to note that not every gene patent would amount to a research tool.

⁹⁰ See text to n 82.

3 Stricter Patentability Criteria

Adopting stricter patentability criteria is yet another way of reducing the potential for blocking patents. This could not only result in a reduction in the scope of protection granted to the patent (consequently increasing the chances of 'inventing around' such claims) but in some cases result in the patent not being granted at all. However, relying on strict examination standards suffers from certain drawbacks:

- i) Firstly, the proposed solution is an ex-ante one. What does one do about all the overbroad patents that have already been issued? It could be argued that some of them could be invalidated.⁹¹ However, invalidation/revocation is not an easy procedure and is also subject to considerable costs.⁹²
- ii) More importantly, the potential of patent law to cater to and deal with blocking concerns that may fructify in future through a circumspect and rather futuristic application of patenting pre-requisites is limited—particularly since most patent offices are faced with a considerable backlog of pending applications.⁹³ In this context, the

⁹¹ 'Nearly half of all litigated patents are held invalid'. JR Allison & MA Lemley 'Empirical Evidence on the Validity of Litigated Patents' (1998) 26 AIPLA Quarterly J 185, 205. See also M Lemley and C Shapiro 'Probabilistic Patents' <http://papers.ssrn.com/paper.taf?abstract_id=567883> (6 November 2004).

⁹² For a good critique of invalidation as an effective means of weeding out bad patents, see J Farrell and RP Merges 'Incentives To Challenge And Defend Patents: Why Litigation Won't Reliably Fix Patent Office Errors And Why Administrative Patent Review Might Help' (2004) 19 Berkeley Tech LJ 1. They highlight the grossly skewed incentives to challenge and defend issued patents and instead recommend, *inter alia* the creation of a cheap and workable administrative post-issue review.

⁹³ Prof Lemley has in fact recommended against expending resources to better the quality of patents granted by the patent office. His argument is that since very few patents are actually litigated or licensed, society would be better off spending its resources in a more searching judicial inquiry into validity in those few cases in which it matters than paying for a more protracted examination of all patents ex ante. In economic terms, the patent office is 'rationally

need for an effective ex-post remedy, such as the doctrine of essential facilities, cannot be overstated.

C MERITS OF A COMPETITION LAW REMEDY

As the above discussion demonstrates, 'internal' remedies within patent law are inadequate to address the blocking or restricted access issue. The doctrine of essential facilities, being a competition law remedy, appears more suited to redress this problem.⁹⁴

- i) Firstly, as mentioned earlier, an optimal resolution of the 'blocking' or 'restricted access' issue involves a significant amount of economic analysis—a task which an antitrust authority is well placed to undertake.⁹⁵
- ii) Secondly, the investigative powers of a competition authority are far superior to that of traditional patent authorities.⁹⁶ In an industry such as the biopharmaceutical one, where industry information is difficult to procure, there are significant advantages in having such a dispute

ignorant' of the objective validity of the patents it issues. See MA Lemley *Rational Ignorance at the Patent Office* 95 Northwestern University Law Review 4 (2001) 1. However for a critique of this, see Farrell and Merges (n 92) who state that the often grossly skewed incentives to challenge and to defend issued patents make this view of Professor Lemley (that ex-post litigation would solve the problem of bad patents) too optimistic.

⁹⁴ Chapters IV and V will explain this doctrine in greater detail and demonstrate how it could potentially address this issue in a more optimal manner. It needs to be noted however that a full fledged comparison cannot be undertaken at this stage, as this paper delves into only one of the limbs of the essential facilities doctrine—namely that of 'essentiality' or 'indispensability'.

⁹⁵ Text to n 10. This is a hypothesis that can be validated only after I have applied the essential facilities doctrine in its entirety to the blocking dilemma.

⁹⁶ For a good discussion of the investigative powers of the European Commission, see A Tissot-Favre 'The Investigative Powers Of The European Commission' (2003) 14(10) Intl Company and Commercial L Rev 319.

resolved by a body that has the ability to investigate and call for information with ease.⁹⁷

- iii) It could also be argued that a compulsory licence on the grounds of anticompetitive behaviour is accorded far greater latitude under TRIPS than are other traditional compulsory licensing grounds—most of which are subject to the procedurally burdensome requirements spelt out in Article 31 (k).⁹⁸

Having said this, it is also important to recognise that the application of an antitrust remedy can at certain levels be more burdensome than resorting to internal remedies within patent law. Illustratively, in the context of application of the essential facilities doctrine, one needs first to establish that the patentee holds a dominant position in the market. This is a fairly complicated task requiring one to define the 'relevant market', establish 'market share' etc. After crossing this hurdle, one has to demonstrate that the refusal to license amounts to an abuse. These aspects will be dealt with in the next chapter.

⁹⁷ In the context of the concerns over exclusive licensing practices with respect to disease gene patents, a recent paper states that 'extremely little is known about the licensing behaviour of firms and universities'. See Henry et al 'Pilot survey on the licensing of DNA inventions' 442. *Journal of Law, Medicine and Ethics*, 31 (2003) 442.

⁹⁸ J Berger 'Advancing Public Health By Other Means: Using Competition Policy To Increase Access To Essential Medicines' ICTSD-UNCTAD Dialogue on Ensuring Policy Options for Affordable Access to Essential Medicines (Bellagio 12-16 Oct 2004) (copy on file with author).

CHAPTER IV

THE ESSENTIAL FACILITIES DOCTRINE: A FRAMEWORK FOR ASSESSING ESSENTIALITY/INDISPENSABILITY

With me everything turns into mathematics—Rene Descartes

The doctrine of essential facilities is designed to deal with the danger that a monopolist in control of a scarce resource will extend its monopoly power vertically from one level of production to another. In its application to intellectual property, this doctrine has not met with a particularly warm welcome.

This doctrine originated in the US⁹⁹ and has been most widely applied in regulating access to physical infrastructure such as transport facilities¹⁰⁰ and utility networks.¹⁰¹ AG Jacobs summarised the US position in *Bronner*.¹⁰²

The US essential facilities doctrine has developed to require a company with monopoly power to contract with a competitor where five conditions are met. First, an essential facility is controlled by a monopolist. A facility will be regarded as essential when access to it is indispensable in order to compete on the

⁹⁹ For an excellent analysis of this doctrine in the US context, see AB Lipsky and G Sidak 'Essential Facilities' (1999) 51 Stan L Rev 1187. See also R Pitofsky D Patterson and J Hooks 'The Essential Facilities Doctrine Under U.S. Antitrust Law' (2002) 70 Antitrust LJ 443.

¹⁰⁰ *United States v Terminal Railroad Association* 224 US 383 (1912). This case pertained to railroad bridges serving the town of St Louis.

¹⁰¹ *MCI Communications v AT&T* 708 F 2d 1081 (7th Cir 1983) (where a local telecommunications network was ordered to provide access to its facility) and *Otter Tail Power Co v United States* 410 US 366 (1973) (where the essential facility in question was a local electricity network).

¹⁰² *Bronner AG* (n 11) [47].

market with the company that controls it... Secondly, a competitor is unable practically or reasonably to duplicate the essential facility. It is not sufficient that duplication would be difficult or expensive, but absolute impossibility is not required. Thirdly, the use of the facility is denied to a competitor. That condition would appear to include the refusal to contract on reasonable terms. Fourthly, it is feasible for the facility to be provided. Fifthly, there is no legitimate business reason for refusing access to the facility. A company in a dominant position which controls an essential facility can justify the refusal to enter a contract for legitimate technical or commercial reasons. It may also be possible to justify a refusal to contract on grounds of efficiency.

With the Supreme Court's recent expression of hostility towards this doctrine in *Trinko*,¹⁰³ the extent of applicability of this doctrine in the US is not clear. It has however come to gain prominence in Europe,¹⁰⁴ with the ECJ delivering a much-awaited decision last year.¹⁰⁵

A EUROPEAN POSITION: ARTICLE 82

¹⁰³ *Verizon Communications Inc v Curtis V Trinko* LLP 540 US 682 (2004) (hereafter 'Trinko') dealt with a complaint against a local telephone monopolist that had refused to deal with its rivals. The Supreme Court observed that the essential facilities doctrine had been 'crafted by some lower courts' and found that there was no need to either recognize it or to repudiate it here. It reasoned that that the Telecommunications Act's extensive provision for access to an incumbent's network 'makes it unnecessary to impose a judicial doctrine of forced access' (880-81).

¹⁰⁴ See JT Lang 'Defining Legitimate Competition: Companies' Duties to Supply Competitors and Access to Essential Facilities' (1994) 18 *Fordham Intl LJ* 437, 439.

¹⁰⁵ *IMS Health GmbH & Co OHG v NDC Health GmbH & Co KG* (C418/01) [2004] All ER (EC) 813 (ECJ (5th Chamber)) (hereinafter 'IMS (ECJ)').

The essential facilities doctrine derives from Article 82 of the EC (European Community) Treaty,¹⁰⁶ which prohibits the abuse of a dominant position. This article reads:

Any abuse by one or more undertakings of a dominant position within the common market or in a substantial part of it shall be prohibited as incompatible with the common market insofar as it may affect trade between member states. Such abuse may, in particular, consist in:

- (a) directly or indirectly imposing unfair purchase or selling prices or other trading conditions;
- (b) limiting production, markets or technical development to the prejudice of consumers;
- (c) applying dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;
- (d) making the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.

As can be seen from the above, Article 82 requires an abusive act¹⁰⁷ by a 'dominant'¹⁰⁸ undertaking within the EC or a substantial part of it¹⁰⁹ in a manner that actually or potentially affects trade between Member States.¹¹⁰

¹⁰⁶ The UK parallel is in section 18(1) of the Competition Act 1988 (the Chapter II prohibition) (hereafter 'UK Competition Act').

¹⁰⁷ As held in *Compagnie Maritime Belge Transports SA v Commission* [2000] ECR I-1365, the list proposed in Article 82 is not exhaustive.

¹⁰⁸ The ECJ has defined 'dominance' as 'a position of economic strength enjoyed by an undertaking which enables it to prevent effective competition being maintained on the relevant

Thus, 'dominance' per se is not prohibited under Article 82; rather, it is only the 'abuse' of such dominance that triggers the application of Article 82. A refusal to provide access to an essential facility could, in certain circumstances, tantamount to an 'abuse'.

An examination of some of the 'essential facilities' or 'refusal to supply' cases will help us understand the parameters of this doctrine better, particularly in its application to intellectual property. It is important to note in this context that the courts have never expressly used the term 'essential facilities doctrine'¹¹¹—rather it appears that most such issues were dealt with under the broad rubric of 'refusal to supply' cases, originating as far back as *Commercial Solvents*.¹¹² Indeed, there is considerable debate on whether the European courts have accepted or endorsed an essential facilities doctrine. Therefore, as stated in the introduction, this paper will use the term 'essential facilities doctrine' merely as a label, assuming that this term is what most closely captures the principles and

market by affording it the power to behave to an appreciable extent independently of its competitors, its customers and ultimately of the consumers'. Case 85/76 *Hoffmann-La Roche* [1979] ECR 461.

¹⁰⁹ For a discussion on this term, see Case 40/73 *Suiker Unie v Commission* [1975] ECR 1663.

¹¹⁰ Case 6/73 & 7/73 *Instituto Chimiotropico Italiano SpA and Commercial Solvents Corporation v Commission* [1974] ECR 223 [30] – [35] which held that conduct could be said to have an effect on interstate trade when it altered the competitive structure of the market.

¹¹¹ See n 11. 'The courts have never acknowledged the existence of an essential facilities doctrine separate from the principle of refusal to supply set out in *Commercial Solvents v Commission*'. See D Aitman and A Jones 'Competition Law And Copyright: Has The Copyright Owner Lost The Ability To Control His Copyright' (2004) 26(3) EIPR 137. The Commission has however referred to the essential facilities doctrine in some of its decisions, beginning with *Sea Containers Ltd / Stena Sealink* [1994] OJ L15/8.

¹¹² Cases 6&7/73 *Commercial Solvents v Commission* [1973] ECR 223; [1974] 1 CMLR 309. It was held here that an undertaking in a dominant position as regards production of a raw material could not cease supplying an existing customer who manufactured derivatives of the raw material simply because it had decided to start manufacturing the derivative itself and wished to eliminate its former customer from the market.

propositions laid down in the refusal to deal (or analogous) cases by the European Commission and courts.¹¹³

My focus will be on only one of the limbs of this doctrine, albeit the most fundamental one—the requirement of ‘essentiality’ or ‘indispensability’.¹¹⁴ More specifically, my effort will be to analyse case law and derive a framework for determining the ‘essentiality’ or ‘indispensability’ of a ‘facility’.

1 *Volvo v Veng*

In terms of the application of the essential facilities doctrine to intellectual property cases, a good starting point is *Volvo v Veng*.¹¹⁵ The case concerned the front wings of the Volvo series 200 cars, on which Volvo held a registered design. Veng, a British company imported these products, manufactured reproductions of them, and marketed them in the UK without authority from Volvo. Upon Volvo instituting proceedings for an infringement of its registered design, Veng argued that by refusing access to its design, Volvo committed an abuse of its dominant position.

The ECJ stressed that a refusal to grant a licence to a third party would not, by itself, constitute an abuse of a dominant position. Rather, Article 82 requires factors over and above a mere refusal to license. Illustratively, the ECJ held that a refusal to license might be abusive, if coupled with:

- (1) an arbitrary refusal to supply spare parts to independent repairers;

¹¹³ See n 11. See also Lang (n 104) 483 who notes, in relation to the term ‘essential facilities doctrine’ that the ‘concept may be merely a useful label ... rather than an analytical tool’.

¹¹⁴ As regards the other limbs of this doctrine or of Article 82 in general, I will, for the purpose of this paper, assume that they stand satisfied. Thus for example, it would be assumed that the alleged abusive act is ‘committed within the EC or a substantial part of it’, the said act ‘affects trade between Member States’ etc.

¹¹⁵ Case 238/87 *Volvo v Veng* [1988] ECR 6211; [1989] 4 CMLR 122.

- (2) overcharging for spare parts; or
- (3) ceasing to produce spare parts for a particular model when there were many vehicles of that model still on the road.¹¹⁶

2 *Magill v BBC*

Magill is the first EC case in which a refusal to license an intellectual property right (IPR) was held to constitute an abuse under Article 82.¹¹⁷

Magill published a weekly television guide containing programme schedules for all the television channels in Ireland. At that time, the broadcasting and television stations, RTE, BBC and ITV (hereafter 'broadcasters') published separate weekly guides to their own programmes. All of them supplied programme information free to daily newspapers, which were allowed to publish one day's listings (or two days' listings at weekends or where the following day was a public holiday). However, publication of the weekly listings was not authorised—the broadcasters had reserved this right for themselves relying on Irish copyright rules. The broadcasters successfully sought an injunction to prevent the continued publication of the Magill comprehensive weekly guide on the basis that, as literary works and compilations, the schedules were entitled to copyright protection.

Magill lodged a complaint with the Commission alleging that the broadcasters refusal to license the weekly listings amounted to an abuse within the meaning of Article 82. The Commission found that the broadcasters had abused their

¹¹⁶ *ibid* [9].

¹¹⁷ *Magill TV Guide* [1989] OJ L78/43, affirmed by the CFI in Case T-69/89 *RTE v European Commission* [1991] ECR II-485, [1991] 4 CMLR 586; Case T-76/89 *ITP v European Commission* [1991] ECR II-575, [1991] 4 CMLR 475; Case T-70/89 *BBC v European Commission* [1991] ECR II-535, [1991] 4 CMLR 669; affirmed by the ECJ in Joined Cases C 241 & 242/91 P *RTE and ITP v. European Commission* [1995] ECR I-743, [1995] 4 CMLR 718 (the ECJ decision will hereafter be referred to as 'Magill'). See n 71.

respective dominant positions on the market; their refusal had prevented the introduction onto the market of a new product for which there was substantial potential demand. It therefore ordered that the broadcasters license each other and third parties on a non-discriminatory basis, a decision confirmed by the Court of First Instance (hereafter 'CFI') and the ECJ.

The ECJ began by cautioning that mere ownership of an intellectual property right would not, by itself, confer 'dominance'.¹¹⁸ However, in this particular case, the court found that the broadcasters were in a 'dominant position', as they enjoyed a de facto monopoly over the television programme information used to compile listings.¹¹⁹

In coming to the conclusion that there was an abuse of a dominant position, the court reiterated the principle in *Vo/vo* that a mere refusal to license would not constitute an abuse—rather, there have to be certain 'exceptional circumstances', which in this case, were articulated by the court as follows:

- i) The broadcasters' refusal to license television listings prevented the emergence of a new product (a 'comprehensive TV guide'), 'which the broadcasters did not offer and for which there was a potential consumer demand.'¹²⁰
- ii) There was 'no justification for such refusal either in the activity of the television broadcasting or in that of publishing television magazines'.¹²¹
- iii) The broadcasters, by denying access to 'the raw material indispensable for the compilation' of a TV guide, 'reserved to

¹¹⁸ Magill (n 71) [46].

¹¹⁹ *ibid* [47].

¹²⁰ *ibid* [54].

¹²¹ *ibid* [55].

themselves the secondary market of weekly television guides by excluding all competition on that market'.¹²²

Therefore, the refusal was an abuse under Article 82(b). However what was not clear from the above was whether the conditions constituting the 'exceptional circumstances' were cumulative or distinct—if cumulative, then one needed all three conditions to be satisfied prior to making a determination that a refusal to grant a license amounts to an abuse. This issue was later resolved (in favour of the conditions being 'cumulative' ones) by *IMS*.¹²³

By evolving an 'exceptional circumstances' framework, *Magill* was perhaps the first case which helped identify some parameters to assist in a determination of when a refusal to license an intellectual property would constitute an abuse.

It may be suggested that implicit in the *Magill* judgement was a belief that copyright in a mere television listing did not merit intellectual property protection. In the words of a commentator:

The low intrinsic value of the right was not expressly mentioned in the *Magill* case by the Courts (their role is not to comment on the appropriateness of national copyright rules)...It was, however, clearly part of the equation.¹²⁴

¹²² *ibid* [56].

¹²³ *IMS (ECJ)* (n 105). The *IMS* case will be discussed in detail later in this chapter.

¹²⁴ IS Forrester 'Compulsory licensing in Europe: A Rare Cure to Aberrant National Intellectual Property Rights?' DOJ/FTC Hearings <<http://www.ftc.gov/opp/intellect/020522forrester.pdf>> (14 September 2004) 12. This underlying assumption was also hinted at by AG Jacobs in *Bronner (AG)* (n 11) [63] when he stated that 'the provision of copyright protection for programme listings was difficult to justify in terms of rewarding or providing an incentive for creative effort.'

It must be noted that a key factor underlying this judgment was that of 'essentiality' or 'indispensability' i.e. the weekly listings were not reasonably and practically replicable—and no amount of innovation could have produced an alternative. In the court's words, they were 'indispensable raw material'.¹²⁵ Surprisingly, the court never expressly articulated this as a separate factor—however it clearly was an underlying assumption that informed the judgment. It was not until *Ladbroke* and more importantly, *Bronner* that the European courts began fleshing out the concept of 'essentiality' or 'indispensability'.

3 Tierce Ladbroke v PMU

The main issue in *Ladbroke*¹²⁶ was whether or not a refusal by PMU (a French horse racing enterprise), to license audiovisual recordings of French horse races to Ladbroke's Belgian betting shops amounted to an abuse of a dominant position. The Commission found in favour of PMU.

Upholding the Commission's decision, the CFI rejected an attempt by Ladbroke to invoke *Magill* for two primary reasons:

- i) PMU was not present on the betting market in Belgium.
- ii) The sound and pictures of the races were not 'essential' for Ladbroke's activity.¹²⁷

The CFI went on to apply the 'essentiality' limb thus:

¹²⁵ *Magill* (n 71) [53].

¹²⁶ Case T-504/93 *Tierce Ladbroke v Commission* [1997] ECR II-923; [1997] 5 CMLR 309.

¹²⁷ *ibid* [131].

In this case, as moreover the Commission and the interveners have pointed out, the televised broadcasting of horse races, although constituting an additional, and indeed suitable, service for bettors, it is not in itself indispensable for the exercise of bookmakers' main activity, namely the taking of bets, as is evidenced by the fact that the applicant is present on the Belgian betting market and occupies a significant position as regards bets on French races. Moreover, transmission is not indispensable, since it takes place after bets are placed, with the result that its absence does not in itself affect the choices made by bettors and, accordingly, cannot prevent bookmakers from pursuing their business.¹²⁸

4 *Oscar Bronner v Mediaprint*

Although no 'intellectual property' was at issue in *Bronner*, the case is extremely significant, as perhaps the first one to engage with the 'essentiality' limb in some detail and draw out a robust framework for its assessment.

In this case, Bronner alleged that Mediaprint was abusing its dominant position by refusing to include his publication in its distribution network. The key issue was whether the Mediaprint's nation-wide home-delivery network for newspapers constituted an 'essential facility'.

The ECJ reiterated that a refusal to license is abusive only in 'exceptional' circumstances—if the conditions below were satisfied:

¹²⁸ *ibid* [132].

- i) The refusal to give Bronner access to Mediaprint's home-delivery system would be likely to eliminate all competition in the daily newspaper market;
- ii) Such refusal could not be objectively justified; and
- iii) The home-delivery service was indispensable to carrying on Bronner's business, inasmuch as there was no actual or potential substitute in existence for that home-delivery service.¹²⁹

On the facts of the case, however, the ECJ did not regard the above conditions as being satisfied, particularly the third condition pertaining to 'essentiality' or 'indispensability'.¹³⁰ The court elaborated on this by stating that:

Moreover, it does not appear that there are any technical, legal or economic obstacles capable of making it impossible, or even unreasonably difficult for any other publisher of daily newspapers to establish, alone or in cooperation with other publishers, its own nationwide home-delivery scheme and to use it to distribute its own daily newspapers.¹³¹

The court also found that other methods of distribution, such as by post and by sale in shops or kiosks, was available, even if they constituted less advantageous means of distribution. In this sense, the court was stressing the fact that a 'mere disadvantage' would not constitute an 'economic obstacle'. Further, in order to accept the existence of economic obstacles, it had to be established that the creation of products or services by a competitor was not

¹²⁹ *ibid* [41].

¹³⁰ Case C-7/97 *Oscar Bronner v Media Print GmbH* [1998] ECR I-7791. This case came up before the ECJ as a referral from the Oberlandesgericht Wien (Higher Regional Court, Vienna), in its capacity as the Kartellgericht (Court of first instance in competition matters).

¹³¹ *ibid* [44].

economically viable for production on a scale comparable to that of the undertaking which controlled the essential facility in question.¹³²

The ECJ also pointed out that the test of 'economic feasibility' was an objective one—Bronner had to show that it was not only Bronner that could not develop an alternative home-delivery system, but that an alternative home-delivery system was not a realistic option for any of Mediaprint's actual or potential competitors in the daily newspaper market.¹³³

It also bears mention that AG Jacobs had pointed out in his opinion that the very fact that Bronner's newspaper had a significant circulation in the market meant that Mediaprint's facility was not an 'essential' one to which Bronner needed access in order to compete effectively in the market.¹³⁴

(a) *Bronner* Framework

Bronner represents the first case where the court focussed on the 'essentiality' or 'indispensability' limb of the essential facilities doctrine and attempted to map out a framework for assessing 'essentiality'. This framework can be crystallised in terms of the following propositions:

- i) Legal, Technical and Economic obstacles: A facility is essential only when duplication of the facility or creation of an alternative is impossible or extremely difficult owing to legal, technical and economic obstacles.

¹³² *ibid* [46].

¹³³ The AG had while stating this in similar terms reiterated the broad underlying theme that competition law was to protect competition in the market and not individual consumers. See *Bronner (AG)* (n 11) [58].

¹³⁴ '...that conclusion is borne out by the claims made in *Der Standard* itself that 'the "Standard" is enjoying spectacular growth in terms of both new subscriptions (an increase of 15%) and placement of advertisements (an increase of 30% by comparison with last year)'. *ibid* [67].

- ii) Economic Viability Standard: While assessing the economic viability of of an alternative 'facility', one has to assume that the business operations (via the facility) of the competing undertaking would be on a scale comparable to that of the undertaking that owns the existing facility. In other words, as was the case in *Bronner*, it is not enough to argue that an alternative facility is not economically viable by reason of the small circulation of the competitors' daily newspaper or newspapers.
- iii) Mere Disadvantage: Mere economic disadvantage is not the same as 'economic non viability' and will not count while categorising something as an essential facility.
- iv) Objective Assessment: While assessing 'viability', the test has to be an objective one—not merely whether it would be non-viable for the undertaking requesting access to the 'essential facility', but whether it would not be so viable for any other party wishing to compete.

5 *IMS Health v NDC*

This case involved a series of proceedings, some before the European Commission/courts and some before national courts. The key issues were referred to the ECJ, which handed down its judgment last year.¹³⁵

IMS Health is a world leader in data collection pertaining to pharmaceutical sales and prescriptions. In pursuance of its business, it created a brick structure ('1860 brick structure'), which segments Germany into sales zones or bricks. The

¹³⁵ *IMS (ECJ)* (n 105).

idea underlying the brick structure is to partition Germany into the maximum number of geographical units that permits data collection without the ability to match the data to a specific pharmacy—as this would contravene German data protection rules.¹³⁶ The 1860 brick structure soon developed into a ‘de facto industry standard’ and came to be widely used by German pharmaceutical companies to analyse sales trends, measure market shares, and gauge the performance of sales representatives.¹³⁷ IMS claimed copyright over its brick structure and successfully brought actions before the German courts against competitors using such structure.¹³⁸

During the course of these national proceedings, one competitor, NDC complained to the Commission and alleged that a refusal to license the brick structure by IMS amounted to an abuse under Article 82. The Commission found in favour of NDC and passed an interim order requiring IMS to grant a licence to competitors.¹³⁹

(a) Commission Decision

The Commission’s decision in large part turned on the fact that certain obstacles made it almost impossible for competitors to create a new structure for regional

¹³⁶ In Germany, data privacy protection rules (Federal Data Protection Act [Bundesdatenschutzgesetz] as most recently amended on 23 May 2001) require that at least three pharmacies be aggregated. See *IMS I* (n 68) [14].

¹³⁷ *ibid* [89].

¹³⁸ In particular, the Landgericht Frankfurt am Main (Frankfurt District Court) had granted, between October and December 2000, separate injunctions prohibiting NDC (an American multinational company), AzyX (a much smaller Belgian company) and Pharma Intranet Information (PI) from using structures derived from the 1860 brick structure on the basis that IMS enjoyed copyright protection. This injunction was however modified slightly subsequently by an appellate court to permit some alternative structures. This ruling coupled with the fact that NDC Health’s market position improved (such that there was no longer any urgency) led the Commission to subsequently withdraw the interim measures on August 13, 2003. See Commission Decision 2003/741 [2003] OJ L268/69 (hereafter ‘*IMS II*’).

¹³⁹ See *IMS I* (n 68).

sales data in Germany. These obstacles could be categorised in the Bronner mould as 'legal, technical and economic' obstacles.

(i) Economic Obstacles:

Of the various obstacles that made it impossible or extremely difficult to create an alternative brick structure, the economic ones are perhaps the most significant and will therefore be dealt with first. The key economic obstacle stemmed from the fact that the copyrighted 1860 brick structure was akin to a de facto industry standard, to which competitors were effectively 'locked in'.¹⁴⁰ The substantial role played by the pharmaceutical companies, alongside IMS, in the design of the 1860 brick structure contributed to the creation of this relationship of dependency.¹⁴¹

Consequently, availing of another structure would have entailed significant 'switching' costs by customers (pharmaceutical companies). More specifically:

- i) A new structure would have entailed changing the territories in which sale representatives operated,¹⁴² leading to:
 - a. Disruptions in existing relationships between sales representatives and the doctors that they routinely visited.
 - b. Modification of employment agreements between the pharmaceutical companies and their sales representatives.

¹⁴⁰ *ibid* [86]-[92].

¹⁴¹ 'The input which the pharmaceutical companies have made to the structure have contributed greatly to its status as a de facto industry standard and to their current dependence on this structure as a format for the receipt of regional sales data services.' *IMS I* (n 68) [185].

¹⁴² *ibid* [89].

- ii) An alternative brick structure would have also necessitated the costly modification of existing software used by pharmaceutical companies.¹⁴³

As the Commission succinctly summed up:¹⁴⁴

The pharmaceutical companies have become locked in to this standard such that to switch away from it to buy sales data formatted in a non-compatible structure, whilst theoretically possible, would be an unviable economic proposition.

(ii) Legal Obstacles:

The legal obstacles presented themselves in the form of:

- a) copyright law, which prevented the creation of structures, similar to the 1860 brick structure;¹⁴⁵ and
- b) data protection law, which limited the number of ways in which copyright in the 1860 structure could be circumvented by the creation of alternatives.¹⁴⁶

(iii) Technical Obstacles:

¹⁴³ *ibid* [122].

¹⁴⁴ *ibid* [92].

¹⁴⁵ See *IMS I* (n 68) [143]-[145]. Although the decision of the German lower court (holding the competing structures to be copyright violations) was under appeal, the Commission assumed for the purpose of its analysis that there was considerable 'legal uncertainty' that placed significant constraints on the creation of alternatives. See text to n 167.

¹⁴⁶ 'On balance, and in the context of these interim measures proceedings, the Commission considers that there is a probability that German data protection laws do impose certain constraints on the construction of a second structure in Germany. See *IMS I* (n 68) [142].

The need to respect postcode boundaries was highlighted by the Commission as a prominent technical obstacle rendering the creation of an alternative an 'impossible' or 'extremely difficult' task. As the Commission explained:

[T]here are clearly very strong reasons for using postcodes as the basis for a structure. Other data with which pharmaceutical sales data is integrated is provided in this format; it appears the only practical way to allocate doctors and pharmacies to particular bricks....¹⁴⁷

The Commission therefore concluded that '...the clear importance of using postal code areas limits the choices available to potential designers of new brick structures'.¹⁴⁸

(iv) Finding:

Based on all the above, the Commission found that:

In this case, in the specific and exceptional circumstances in which the "1860 brick structure" was developed and copyright was asserted and found to subsist, the work in question for the technical, legal and economic constraints referred to above is incapable of being replicated by means of a non-infringing parallel creation.¹⁴⁹

(b) CFI Decision

The President of the CFI suspended the Commission decision on the ground that

¹⁴⁷ [133].

¹⁴⁸ [132].

¹⁴⁹ *IMS I* (n 68) [184].

the Commission seemed to take a fairly liberal view of the notion of 'exceptional circumstances' articulated in *Magill*.¹⁵⁰ In particular, the CFI was concerned that the Commission regarded the *Magill* conditions as non-cumulative i.e. the Commission did not regard it as necessary that the refusal to license should prevent the emergence of a 'new product or service' for which there was 'potential consumer demand'.¹⁵¹ It is to be noted however that this order of the CFI did not overrule the Commission's assessment of 'essentiality' or 'indispensability' of the 1860 brick structure.

(c) The ECJ Decision

As mentioned earlier, it was during the course of national proceedings that IMS had complained to the Commission. The Commission's ruling was appealed to the CFI and thereafter to the ECJ. During the course of these proceedings, the national courts referred certain questions separately to the ECJ under Art 234 of the EC Treaty, which are summarised below:

- i) Whether the mere refusal by IMS Health to license a brick structure that was akin to an industry standard would contravene Article 82?¹⁵²
- ii) The significance of the pharmaceutical industry's involvement in developing the 1860 brick structure in assessing whether a refusal to license such structure constitutes an abuse; and
- iii) The significance of the 'switching' costs that the pharmaceutical

¹⁵⁰ The President of the Court of First Instance (CFI) provisionally suspended the interim measures on August 10, 2001 and then confirmed this suspension on October 26, 2001 pending the CFI's judgment in the main action under Art 230. See Case T-184/01 R *IMS Health v Commission* [2001] ECR II-2349 and 3193 (hereafter 'IMS III').

¹⁵¹ The Commission had held in this regard: 'As clarified in the *Ladbroke* judgement, there is no requirement for a refusal to supply to prevent the emergence of a new product in order to be abusive'. See *IMS I* (n 68) [180].

¹⁵² Although the word 'standard' was not explicitly used in this question, the notion of a standard was implied.

industry would have to undergo (in switching to an alternative structure) in assessing whether the refusal to license constitutes an abuse.

In answer to the first question, the ECJ stated that mere indispensability (as a 'standard') would not, by itself, constitute 'abuse'. Rather the 'exceptional circumstances' drawn out by *Magill* have to be present. In the court's words:

Therefore, the refusal by an undertaking in a dominant position to allow access to a product protected by copyright, where that product is indispensable for operating on a secondary market, may be regarded as abusive only where the undertaking which requested the licence does not intend to limit itself essentially to duplicating the goods or services already offered on the secondary market by the owner of the copyright, but intends to produce new goods or services not offered by the owner of the right and for which there is a potential consumer demand.¹⁵³

It is important to note that the court also went on to clarify that the *Magill* conditions constituting the 'exceptional circumstances' framework were cumulative. Thus, the court endorsed the CFI objection to the Commission reading the *Magill* conditions as separate and distinct. Also in terms of the traditional two market distinction and the need to identify two distinct markets, the ECJ endorsed the view in *Bronner* that 'it was sufficient that a potential market or even hypothetical market can be identified.'¹⁵⁴

¹⁵³ *IMS (ECJ)* (n 105) [49].

¹⁵⁴ *ibid* [45]. I will however, focus only on the 'essentiality' limb and not deal in any detail with the other aspects of the essential facilities doctrine, as evolved through case law. I will take these factors to be satisfied—in much the same way that I assume at the beginning of this chapter that factors such as conduct 'affecting the EC or a substantial part of it' stand satisfied (see n 114).

To the second and third questions, the ECJ clarified that these factors (customer participation in the development of the standard and 'switching costs' in moving to an alternate structure) would be relevant to an assessment of whether the facility is 'essential' or 'indispensable' in the first place.

In the process of answering these questions, the courts did engage in some discussion of the 'essentiality' or 'indispensability' of the brick structure. The court endorsed the key test in *Bronner* that it had to be established, at the very least, that the creation of an alternative was impossible or extremely difficult owing to legal, technical or economic obstacles. However unlike the Commission, the ECJ did not delve into this issue in detail; rather it categorised the issue of whether the structure constituted an essential facility as a factual one, to be ultimately determined by the national courts. This reluctance stems from the fact that the above issues came up to the ECJ by way of referral from a national court. The Commission, on the other hand, faced no such constraints and therefore engaged with the facts in a more substantial way.¹⁵⁵

B BROAD CONCLUSIONS FROM CASE LAW

Although the parameters of the essential facilities doctrine are yet to be worked out fully by the courts in Europe, some broad conclusions can be drawn from case law.

1. The essential facilities doctrine is a subset of the wider mandate to refrain from abusing a dominant position under Article 82. Prior to a finding that there has been an abuse, 'dominance' in a given market is to be

¹⁵⁵ Being factual issues, it appears that the various obstacles highlighted by the Commission would have been endorsed by the ECJ, had the opportunity presented itself for such a review.

established. The courts have been cautious to state that mere ownership of intellectual property would not, by itself, confer 'dominance'.¹⁵⁶

2. A mere refusal to license an intellectual property is not sufficient to invoke the essential facilities doctrine. Rather, as stressed in *Volvo v Veng*, there have to be additional 'exceptional circumstances'.
3. Although the precise ambit of the 'exceptional circumstances' framework is yet to be articulated by the courts, the contours of this paradigm can in some broad sense be gleaned from cases such as *Magill*, *Bronner* and *IMS*.¹⁵⁷
 - i) New Product: The refusal to grant access to the facility is likely to prevent the emergence of a new product for which there is potential consumer demand;
 - ii) Essentiality: The facility is 'indispensable' to carrying on business, inasmuch as there is no actual or potential substitute for that facility;
 - iii) Objective Justification: The refusal is not capable of being objectively justified; and
 - iv) Secondary market: The refusal is likely to foreclose all competition in the secondary market.

Notwithstanding the above factors, an English case held that the 'exceptional circumstances' factors drawn out by the EC courts are not exhaustive but could

¹⁵⁶ *Magill* (n 71) [46].

¹⁵⁷ *IMS* clearly reiterates that the 'exceptional circumstances' test is here to stay. See B Lebrun 'IMS v NDC: Advocate General Tizzano's Opinion' 26 (2) (2004) EIPR 84.

admit of other situations as well in future.¹⁵⁸ The UK Court of Appeal observed that this approach was warranted by the 'width of the descriptions of abuse contained in Article 82 itself'.¹⁵⁹

Of all the 'exceptional circumstances' factors, the one that truly underpins the very essence of the essential facilities doctrine is 'essentiality' or 'indispensability'. Needless to state, if the facility is non-essential, one does not need to examine the other limbs of this doctrine.

'Essentiality' formed a significant portion of the underlying judicial reasoning in *Magill*¹⁶⁰ *Bronner* and *IMS*. In *Magill*, the weekly listings were not reasonably and practically replicable – they were very 'essential' and no amount of innovation could have produced an alternative.¹⁶¹ In *Bronner*, the ECJ stipulated a high threshold for 'essentiality', holding that mere inconvenience in duplicating the 'essential facility' in question would not suffice. In *IMS*, the Commission found that the copyrighted 1860 brick structure had acquired the status of a de facto industry standard and that this precluded the creation of viable substitutes by competitors. It is pertinent to note that although *Magill* and *IMS* were copyright cases and *Bronner* didn't even involve an intellectual property, to the extent that they lay down a broad framework for determining 'indispensability' or 'essentiality', their principles could be transposed to patent cases as well.

¹⁵⁸ *Intel Corp v VIA Technologies Inc* [2002] EWCA Civ 1905. For an analysis of this decision, see D Curley 'Eurodefences and Chips—"A Somewhat Indigestible Dish": The UK Court of Appeal's Decision in *Intel Corp v Via Technologies*' (2003) 25 (6) EIPR 282. See also n 235.

¹⁵⁹ *Intel* (n 158) [48].

¹⁶⁰ Apart from *Bronner*, most other cases including *Magill* do not appear to have treated 'essentiality' seriously enough, at least to the extent of discussing this limb first before moving on to the other limbs. However as mentioned earlier, although essentiality or indispensability was not explicitly stated as a separate factor in *Magill*, it was clearly part of the 'exceptional circumstances' equation and an important prerequisite on which the finding of abuse was based.

¹⁶¹ In fact, in this case, even attempting an alternative would have been illogical—as a compilation of television listings would always require the listings to be reproduced.

1 Assessing 'Essentiality': Legal, Technical and Economic Viability

Bronner was the first case to elucidate a broad framework for assessing the essentiality or indispensability of a facility. The *Bronner* framework has already been crystallised as propositions at an earlier point in this chapter.¹⁶² Amongst these propositions, the critical one and perhaps the most difficult to assess is the existence of 'legal, technical or economic obstacles' that would render the creation of an alternative facility an 'impossible' or 'extremely difficult' task. Quite clearly, all the three parameters (legal, technical and economic) have to be assessed in order to make a final determination of the essentiality or indispensability of a facility. For the sake of generating an easy to use and a somewhat 'mathematical' framework, I have, while attempting to retain the essence of the *Bronner* framework, adapted it in two significant ways:

- i) I have adapted the proposition that 'the creation of the facility must be impossible or extremely difficult owing to legal, technical or economic obstacles' to the proposition that 'the alternative facility should be non viable—from a legal, technical and economic standpoint'. It would appear that 'viability' most closely represents what the ECJ had in mind while discussing the 'impossibility' or 'extreme difficulty' in creating alternatives.
- ii) Neither *Bronner* nor any of the other cases have laid down any specific order for assessing the viability of an alternative or substitute. This paper therefore proposes the following order:
 - a) Determining the legal viability of an alternative facility.
 - b) Assuming the alternative is legally viable, evaluating the technical viability.

¹⁶² Text after n 134.

- c) If from a technical standpoint, the alternative is viable, then assessing the economic viability of the alternative.

(a) Legal Viability

The above order has some advantages. For one, assessing what constitutes a 'legal' obstacle would be a relatively easier and more objective task for a competition authority or a judge, than assessing what constitutes 'technical' or 'economic' obstacles. Illustratively, in *Magill*, the 'legal viability' assessment was fairly straightforward. Any alternative facility would have 'infringed' the broadcasters' copyright, as such facility would have had to replicate the television listings. The 'legal' obstacle therefore was one that was impossible to transcend.

Having said this, it is important to note that *Magill* was an exception and that not every case pertaining to intellectual property is likely to present such a clear-cut analysis of 'legal viability'. In fact, a good number of 'essential facilities' (protected by intellectual property) would admit of some amount of 'inventing around' or 'designing around'.

Estimating the exact latitude that exists for such designing around is a complex task— we are offered a glimpse of this complexity in *IMS*. The Commission had initially based its interim order (mandating access to the 1860 brick structure), in part, on a ruling by a German lower court that had upheld IMS's copyright over its brick structure and found competing structures to be infringing.¹⁶³ The Commission concluded from this that alternatives to the 1860 brick structure were not 'legally viable'.

¹⁶³ See n 138.

However at a later point in time, an appellate court in Germany qualified the findings of the lower court in relation to the scope of copyright over the 1860 structure and seemed to suggest that some of the competing structures would not infringe.¹⁶⁴ In pertinent part, it held that:

[T]he defendant or third parties could not simply be prohibited from developing freely and independently a brick structure that is similarly based on a breakdown by district, urban district and post-code district and for that reason comprise more or less the same number of bricks...¹⁶⁵

This finding by the appellate court, along with other factors convinced the Commission to withdraw its interim order.¹⁶⁶ One way of resolving such complexities could be by relegating all borderline cases to the category of 'legally' non-viable—as any substitute would be 'legally uncertain'. In fact, the Commission in *IMS* adopted such an approach:

...the Frankfurt Court judgement of 28 December 2000 gave an injunction preventing the selling of data in both the 2847 and 1860 segments and any other number of segments so far as it constitutes a derivative from RPM 1860. The Court did not define precisely what it would consider to be derivatives, and no clarification is likely for around 3 years. Pharmaceutical companies are aware of this uncertainty, having been warned by IMS not to infringe its copyright, and would be skeptical about the legality of

¹⁶⁴ See *IMS II* (n 138).

¹⁶⁵ Translated version of the judgment. See *IMS II* (n 138) [10].

¹⁶⁶ See n 138.

any new structure which competitors of IMS might use to format a new regional sales data service.¹⁶⁷

Having said this, there is still a significant amount of objectivity associated with assessing 'legal viability'. A non-viable alternative could simply be taken to be any alternative that infringes the intellectual property covering the essential facility in question or one that violates some other law.¹⁶⁸

(b) Economic Viability

Contrast 'legal viability' with 'economic viability', where it is more difficult to agree upon the objective parameters for determining as to when something is 'economically viable'. The Asian Development Bank (ADB) defines 'economic viability' thus:

The assessment that increases in output produced by a project using the least cost method will recover costs, provide an additional required rate of return, and sustain effective production in the face of uncertainty and risk.¹⁶⁹

This begs the question however of what an 'additional required rate of return' would be and what the term 'effective production' would entail.

Another definition is attempted by DN Marvis et al: 'the measure of a systems ability to achieve specified cost and profitability goals as well as satisfy any

¹⁶⁷ *IMS I* (n 68) [143].

¹⁶⁸ Legal 'non-viability' could also stem from the potential to transgress some other law. As shown earlier, in *IMS*, one of the legal obstacles hampering the creation of viable alternative facilities were limitations stemming from data protection law. See n 136 and 146.

¹⁶⁹ *Guidelines for the Economic Analysis of Projects* (Asian Development Bank 1997) <http://www.adb.org/Documents/Guidelines/Eco_Analysis/glossary.asp> (20 December 2004).

constraints imposed'.¹⁷⁰ Here again, one is forced to query as to what the 'specified cost and profitability goals' would be?

As seen from the above, 'economic viability' may not be as objectively determinable as 'legal viability' or even 'technical viability'.¹⁷¹ Therefore, this part of the evaluation is best relegated to the end.

(c) Technical Viability

The ease or difficulty of evaluating 'technical viability' lies somewhere in the middle. In an article analyzing the viability of proposals pertaining to water resources development, 'technical viability' was measured with respect to the physical parameters such as quantity, quality and reliability of source of the water.¹⁷²

In the context of patented genes, the technical viability of a substitute could in accordance with the above physical parameters be measured by asking the following question: Will it (the substitute) be as effective in its function as the patented gene?

It is evident that in the particular context of genetics, which is a relatively nascent and uncertain science,¹⁷³ asking whether an alternative is technically feasible (i.e. can it guarantee the same result) is not an easy task. However, when compared with economic feasibility, it is far more objective—as the basic

¹⁷⁰ DN Mavris, GC Mantis and MR Kirby 'Demonstration of a Probabilistic Technique for the Determination of Aircraft Economic Viability' <<http://www.asdl.gatech.edu/publications/pdf/1997/AIAA-97-5585.pdf>> (2 January 2005).

¹⁷¹ It needs to be mentioned here that although 'economic viability' is not the exact term used in *Bronner*, it is clear that this term echoes most closely what the ECJ had in mind.

¹⁷² AT Wolf & M Murakami 'Techno-Political Decision Making for Water Resources Development: The Jordan River Watershed' (1995) 11(2) *Water Resources Development* 147, 151.

¹⁷³ See n 23.

question can be reduced to: given the current state of technology, is an alternative technically 'possible' or not?

It needs to be noted at this juncture that questions of technical feasibility would, by their very nature, invite issues of economic feasibility, with which they are inexorably linked. However for the purpose of our analysis here, it helps to keep them separate.

To conclude the above discussion, since it is possible to determine the 'legal' viability of an alternative with a higher degree of probability than either its technical or economic counterparts, it would help to have this as the first parameter against which to assess essentiality. Similarly, since 'economic viability' would involve consideration of factors that are less definite than those pertaining to a legal or technical viability analysis, this assessment could perhaps be undertaken last.

CHAPTER V

HOW 'ESSENTIAL' IS A PATENTED GENE?

If necessity has been regarded through the ages as the mother of 'invention'¹⁷⁴— then patent law ought to be considered the mother of 'inventing around'.

As has been stressed in the earlier chapter, the question of 'essentiality' or 'indispensability', in the context of intellectual property would, in large part, hinge upon the availability of substitutes that could be arrived at by 'inventing around'.

A ALTERNATIVES/SUBSTITUTES TO PATENTED GENES

A number of scholars have argued that a patented gene cannot be invented around and that there are no substitutes or alternatives to patented genes. Thus, for example, Dr Matthijs of the Center for Human Genetics in Leuven, Belgium states:

One reason why the market system does not always operate properly in the case of patents on genes is because genes and genetic sequences are different from classical chemical compounds. Genes and genetic sequences have an informational content. One cannot "invent around" the sequence if it is patented, because each

¹⁷⁴ '...and yet the true creator is necessity, who is the mother of our invention.' Plato *The Republic* Translated by Benjamin Jowett <<http://classics.mit.edu/Plato/republic.3.ii.html>> (23 December 2004).

gene and each gene sequence is unique in its kind. Hence, through patenting, a "double" monopoly arises.¹⁷⁵

Similarly, Professor Lori Andrews states:

Moreover, there are fewer downsides to granting a patent on a drug or a medical device than granting a patent on a gene. Other researchers can create alternatives to drugs and devices. There are no alternatives to the patented human genes in genetic diagnosis and gene therapy.¹⁷⁶

My attempt is to cast some doubt on this proposition, at least in so far as it is stated in absolute terms. No doubt, inventing around a 'patented gene' may be considerably more difficult when compared to other patented inventions. However, it is not an 'impossible' task, as illustrated by some of the examples below:

1 Gene Variants/Animal Genes

A patent on a gene could be circumvented by deploying a variant of the gene.¹⁷⁷ In fact, since some animal genes are similar in structure and function to human genes, it may even be theoretically possible to substitute an animal gene for a human one. A recent BBC report stated that scientists discovered a gene in the nematode worm that was similar to the human breast and ovarian cancer gene

¹⁷⁵ G Matthijs 'Patenting Genes May Slow Down Innovation and Delay Availability of Cheaper Genetic Tests' (2004) 329 British Medical J 1358, 1359. See also G Matthijs and D Halley 'European-wide Opposition against the Breast Cancer Gene Patents' (2002) 10 Eur J Human Genetics 783.

¹⁷⁶ LB Andrews (n 55) 78-79. See also LB Westin (n 12 and 24).

¹⁷⁷ I am using the term 'variant' in a wide sense to mean any variant of the original sequence that could perform broadly the same function, whether it belongs to the same family as the original gene (homologous) or not.

BRCA1.¹⁷⁸ Experts opined that this gene could offer some clues regarding the development of breast and ovarian cancer. Given Myriad's high licensing fees and threat to enforce patents strictly even against universities,¹⁷⁹ researchers keen on working in this area could consider using the nematode gene instead. Surprisingly, a similar hypothetical argument seems to have been put forth in a recent article, albeit using the Chimpanzee as an example.¹⁸⁰

However this is not to say that all such substitutes would be 'viable'. Illustratively, they may not work as well as the patented human gene and may therefore fall short of the 'technical viability' threshold. Further, depending on the breadth of the patent claims, some substitutes could fall within the scope of the original patent and consequently fail the 'legal viability' test. This assessment will however be undertaken in more elaborate detail later in this chapter.

2 Gene Switching/Gene Activation

In order to appreciate the ingenuity underlying this method, one has to journey back in time to recollect that the initial grant of gene patents (and indeed even the current ones) was based substantially on a legal sophistry.¹⁸¹ Although the 'gene' itself (as existing in its natural state) could not be patented, once it was

¹⁷⁸ 'Primitive Worm Gives Cancer Clue': <<http://news.bbc.co.uk/1/hi/health/3368685.stm>> (19 September 2004).

¹⁷⁹ S Bunk 'Researchers Feel Threatened by Disease Gene Patents' (1999) 13 (20) *The Scientist* 7.

¹⁸⁰ 'Say you were able to get a gene from a chimpanzee that was close enough to the human BRAC-1 gene to do as good a job at predicting the risk for breast cancer. If the owner of the patent on the use of the human gene screams foul, you can reply that you are using something found in nature, which the Supreme Court has held the patent law cannot rule out'. See 'Having a patent may not protect you' *Red Herring* <<http://www.redherring.com/Article.aspx?a=4341#>> (24 September 2004).

¹⁸¹ For a good critique of this sophistry, see JM Conley and R Makowski 'Back to the Future: Rethinking the Product of Nature Doctrine as a Barrier to Biotechnology Patents' <<http://www.unclaw.com/chin/teaching/patent/S2004/productof%20nature.pdf>> (12 November 2004).

isolated or purified in some form, a magic wand swept it past the 'product of nature' hurdle.¹⁸² Patents were thus issued on 'isolated and purified' DNA sequences (separate from the chromosomes in which they occurred in nature) and on DNA sequences that had been spliced into recombinant vectors or introduced into recombinant cells (of a sort that did not exist in nature).

A patent monopoly therefore would cover only such artificial embodiment of the genetic information and not the 'genetic information' per se. It is this understanding that could offer significant possibilities for 'inventing around' a patented gene. In other words, the very same sophistry used to grant gene patents could now be flipped on its head. If the 'gene' in its natural state (or 'genetic information' per se) cannot be the subject matter of a patent, then surely, turning on a human gene to make a protein while the DNA is still lodged inside the body (or in the nucleus of a human cell in a laboratory dish) would allow someone to work around a patented gene.

This technique popularly referred to as 'gene switching' or 'gene activation'¹⁸³ is coming to be strategically used by companies to design around existing gene patents. Thus for example, Sangamo BioSciences, a California based company designs around gene patents with the help of certain 'zinc finger protein' transcription factors—proteins that turn genes on and off. In order to steer clear of the patent covering the protein itself (since most patents cover not only the gene but also the protein made by the gene), these 'zinc finger' switches have been designed in a way that they could be directly administered to a patient. The zinc finger turns on a gene to express the medically important protein inside

¹⁸² See RS Eisenberg 'Re-Examining the Role of Patents in Appropriating the Value of DNA Sequences' (2000) 49 Emory LJ 783, 786.

¹⁸³ The scientific term for this technique is 'endogenous gene activation'. See G Stix 'Legal Circumvention: Molecular Switches Provide a Route around Existing Gene Patents' (2002) 287 (1) Scientific American 36.

the body, circumventing the need for purifying the protein or removing it from the cell.

(a) *Amgen v TKT*

A more familiar example of 'gene activation' to patent lawyers and scholars would be the creative deployment of such 'switching' technique by TKT to circumvent Amgen's patents on erythropoietin (hereafter 'EPO') and its corresponding gene, spawning a series of law suits on both sides of the Atlantic.¹⁸⁴ EPO is a very important hormone made in the kidney that stimulates the production of erythrocytes (red blood cells) in the bone marrow. It therefore has tremendous utility in the treatment of anaemia, particularly when such anaemia is associated with kidney failure. Unfortunately, the body produces EPO in very small amounts, making it inconceivable to isolate enough natural EPO to treat all anaemic patients.

This is where Amgen's deployment of recombinant DNA (r-DNA) technology for the production of large quantities of human EPO proves immensely useful.¹⁸⁵ Amgen's patented method involves isolating the human EPO gene, introducing it into a cloning vector and then inserting such vector into a host cell (in this case, Chinese Hamster Ovary (CHO) cells) to produce desired amounts of EPO. As will be appreciated, the human EPO DNA in this case is 'exogenous' to the hamster

¹⁸⁴ This legal saga began with the filing of a declaratory judgment action by Kirin-Amgen Inc (hereafter 'Amgen') against Hoechst Marion Roussel Inc and Transkaryotic Therapies (hereafter collectively 'TKT') in the US alleging that TKT's EPO product infringed Amgen's patents. There were proceedings in other jurisdictions as well including the UK, Australia and the Netherlands.

¹⁸⁵ 'r-DNA technology' or Recombinant DNA technology allows the production of proteins in large quantities by a process that is more efficient and less costly than techniques previously used. This is accomplished by (1) isolating DNA containing a particular gene and inserting it into a cloning vector to make a recombinant DNA molecule and (2) inserting the vector into an appropriate host environment to allow propagation of the recombinant DNA, and if desired, expression of the protein product. See Basheer (n 19) 5.

host cell. Amgen holds patents not only on this process for producing EPO but also on the EPO gene and the end EPO product.¹⁸⁶

By contrast, TKT, in producing its human EPO does not use a 'host cell' from a non-human species. Rather, it manipulates the ordinarily unexpressed human EPO gene in a human cell by introducing a 'promoter sequence', which then 'switches on' the EPO coding gene.¹⁸⁷ It needs to be noted that although the EPO gene is present in all human cells, in most cells it is 'dormant' or turned off.

In this sense, as opposed to Amgen's process which relies upon introducing an 'exogenous' DNA sequence into a host cell, TKT employs an exogenous promoter to spur the production of EPO from the 'endogenous' EPO gene. While this key distinction was appreciated in the UK, it failed to convince courts in the US, where TKT was held to infringe. This legal saga will be elaborated upon later in this chapter to demonstrate that even such ingenious switching techniques may not be free of legal risk.

3 Offshore Research

Another strategy that is coming to be increasingly used in the biopharmaceutical industry today is to conduct research involving patented products/processes in offshore jurisdictions where the patentee has failed to procure a patent registration. This strategy received a boost in the United States with the recent

¹⁸⁶ Amgen's EPO product (marketed under the name Epogen) was launched in 1989. Since that time, the product has become a huge success, earning billions of dollars in sales. See Epogen Backgrounder <<http://www.amgen.com/product/epogen/epogenBackgrounder>> (10 September 2004).

¹⁸⁷ See *Kirin-Amgen Inc v Transkaryotic Therapies Inc* (No 2) [2004] UKHL 46; (2004) 148 SJLB 1249 (HL) [10] (hereafter 'Amgen (HL)'). TKT sought to market its product under the name Dynepo. This product is also referred to as HMR 4396 and Gene-Activated EPO ('GA-EPO'). For the sake of convenience, it will be referred to hereafter as 'GA-EPO'.

ruling by the US CFAC in *Bayer AG v Housey Pharmaceuticals*¹⁸⁸ (hereafter 'Housey') that stated that if the result of using a patented process is 'information' and not a 'product', then importing such information into the US would not amount to a patent infringement.

(a) Bayer: US Ruling

Housey owned a number of US patents relating to methods of screening for, or identifying compounds with stimulatory or inhibitory activity against certain proteins—these compounds consequently had the potential for development as pharmaceuticals. Bayer employed the screening method in Europe to identify compounds which were then developed as the active ingredient of certain pharmaceutical compositions. Bayer proceeded to import into and sell in the United States these pharmaceutical compositions. Housey brought proceedings against Bayer for infringement of its US patents under section 271(g).¹⁸⁹ This section reads in relevant part as:

Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent.'

Upholding the dismissal of Housey's complaint by the District Court, the Court of Appeal for the Federal Circuit (CAFC) rejected Housey's argument that information obtained using its patented process was a 'product' within the meaning of the statute. The court clarified that infringement under section

¹⁸⁸ *Bayer AG v Housey Pharmaceuticals Inc* 340 F 3d 1367 (Fed Cir 2003), affirming the decision of the District Court in 169 F Supp 2d 328 (Del 2001).

¹⁸⁹ Section 271(g) (1) of 35 USC 1994 (US).

271(g) is limited to physically manufactured goods, and declined to extend the protection of the statute to information generated by a patented process.¹⁹⁰

Similarly, the court rejected Housey's assertion that a drug discovered by using 'information' derived from a patented process was a 'product of that process'. The court held that section 271 (g) required that 'the process must be used directly in the manufacture of the product, and not merely as a predicate process to identify the product to be manufactured'.¹⁹¹ It therefore concluded that 'a drug product, the characteristics of which were studied using the claimed research processes' was 'not a product "made by" those claimed processes'.¹⁹²

Under *Bayer* therefore, a patentee cannot exclude importation of either 'information' or products not 'directly' obtained from the patented process. Although the imported information in the case of *Housey* was the biological activity of a drug molecule, the decision would seem to apply equally to the importation of other types of information, such as DNA sequence information.

To illustrate this point, consider the example of Synergene, a Maltese company that had been, till recently, conducting diagnostic tests using Myriad's patented BRCA genes and shipping the results ('information') back to customers in countries where the patent existed.¹⁹³ Needless to say, this was possible owing to the fact that Myriad's inventions were not patented in Malta.

Similarly, NimbleGen, a US company is reported to be strategically using the patented processes of Affymatrix to produce custom microarrays from a facility

¹⁹⁰ *Bayer* (n 188) 1376-77.

¹⁹¹ *ibid* 1378.

¹⁹² *id.*

¹⁹³ E Check 'Malta Provides Loophole for Breast-Cancer Screen' (2002) 419 *Nature* 767. Unfortunately, this testing was discontinued by Synergene, owing to what appears to be economic constraints. See n 233.

in Iceland.¹⁹⁴ Since Affymatrix failed to patent its technology in Iceland, NimbleGen conducts its research unhindered in this jurisdiction and then ships the resulting data ('information') back to customers in countries where the technology in question is patent protected. Not too surprisingly, Affymatrix took a keen interest in the *Housey* case and filed an amicus brief, arguing that patent law did not differentiate between 'physical products' and 'information products'.¹⁹⁵

Having said the above, it is important to bear in mind that this strategy may not work indefinitely as companies could opt to patent worldwide, particularly in those countries where technological and infrastructural capabilities enhance attractiveness as an offshore research destination. The laws could also be amended to bring such strategic offshoring within the ambit of patent infringement.

(b) Bayer: UK/EU Position

In much the same way as section 271 of the US Patents Act referred to above, Section 60(1)(c) of the UK Patents Act states that it is an infringement of a patented process to sell, use or import into the United Kingdom a product which is the 'direct' result of a patented process. The section reads as below:

... a person infringes a patent for an invention if ... where the invention is a process, he disposes of, offers to dispose of, uses or imports any product obtained directly by means of that process or keeps any such product whether for disposal or otherwise.

¹⁹⁴ See M Salisbury 'Is Data a Product? Patent Kings Fear IP Goes Outside the Law' *Genome Technology* <<http://www.genomeweb.com/articles/view.asp?Article=20042316229>> (24 September 2004).

¹⁹⁵ *id.*

Although the UK has not seen a *Housey*-like case—where the court was called upon to rule whether a ‘product’ as used in section 60 includes ‘information’, there have been cases dealing with the causal link between the use of the patented process and the imported product. The leading case in this regard is *Pioneer Electronics Capital Inc. v Warner Music Manufacturing Europe GmbH*, discussed below.¹⁹⁶

Pioneer held a patent in the UK for processes relating to the manufacture of master disks, which were used for the mass production of compact disks (CDs). However, the patent covered the process of producing master disks but not the process of producing CDs from the master disks. Pioneer sued Warner for importing CDs into the United Kingdom which had been made outside the United Kingdom from the master disks. Pioneer argued that the CDs were products obtained ‘directly’ from the patented process.

The Court of Appeal upheld the lower court decision that the finished CDs were the result of three further stages of production and were therefore materially different from the master disks. They further noted that neither the master nor any of the intermediate products were capable of performing the same function as the finished disk.¹⁹⁷

It would be fair to state that this decision is broadly reflective of the European position as well.¹⁹⁸ In fact, in reaching its decision, the court held that by virtue

¹⁹⁶ [1997] RPC 757 (CA).

¹⁹⁷ *ibid* 764-65.

¹⁹⁸ When I use the term ‘European position’, I am very generally referring to the principles laid down in European patent instruments such as the EPC and the CPC. Despite the fact that the EPC does not govern the extent of protection and enforcement of European patents in designated countries, it would appear that today there is a growing trend towards consistency across national courts—as national courts are looking more to the European Patent Office (EPO)

of section 130(7) of the Act, section 60(1)(c) had to be construed in line with the EPC. Article 64(2) of the EPC states that:

If the subject-matter of the European patent is a process, the protection conferred by the patent shall extend to the products directly obtained by such process.

Since Article 64(2) has its origins in German law, the court turned to the German Patent Act and found that the German equivalent for the term 'directly' was *unmittelbar*¹⁹⁹—a term similar to 'without intermediary'. The court therefore held that the section applied to products which were the direct and immediate result of the patented process.

It would be interesting to hypothesise how a UK court would decide a *Housey* like case, particularly the 'information' versus 'product' dilemma that the US decision sought to address. Since the wording of the statutory sections are broadly similar, it is reasonable to assume that 'information' derived from the patented process would not constitute a 'product' for the purposes of section 60(1)(c). On the issue of whether a drug discovered by using that information would amount to a 'product' under section 60 (1) (c), *Pioneer* would resolve this issue in favour of *Bayer*. Much like the US decision, it is likely to be held that the direct output of the process is information about the chemical compound and not the chemical compound itself.

B THE 'VIABILITY' ISSUE

and decisions of other member states when determining question of infringement. See G Triton *Intellectual Property in Europe* (Sweet and Maxwell London 1996) 55.

¹⁹⁹ Section 6(2) of the German Patents Act. See *Pioneer* (n 196) 765-66.

I have briefly tried to highlight above some of the ways in which gene patents could be circumvented by the deployment of substitutes/alternatives. However, it remains to be seen whether such substitutes or alternatives would be 'viable'—technically, legally and economically. I will use the *Bronner* framework to aid me in this investigation. As suggested in chapter IV, it may be helpful to do the investigation in this order:

- i) Determining the legal viability of the proposed substitute/alternative;
- ii) Assuming the alternative is legally viable, evaluating the technical viability;²⁰⁰
- iii) If from a technical standpoint, the alternative is viable, then assessing the economic viability of the alternative.

1 Legal Viability

Where the 'essential facility' in question is a patented invention, the key question to be asked when determining 'viability' is: Is the scope of the patent broad enough to cover the proposed substitute or alternative? This is not to say that this question is determinative of the issue in its entirety—other questions such as whether there exists a research exemption and whether such exemption is broad enough (to permit working with the patented gene in question to arrive at the substitute) also need to be asked. First, we discuss patent scope before moving on to the research exemption.

(a) Determining Patent Scope

²⁰⁰ Since the circumvention strategy based on taking research offshore is one that primarily relies on a perceived gap in the law (and such 'gap' has already been discussed), it will not be discussed again under the 'legal viability' section.

Patent claims determine the scope of the monopoly conferred by a patent, but some latitude is permitted in construing them. The extent of such latitude depends on the legal system under consideration. Illustratively, while the US recognizes a doctrine ('doctrine of equivalents') that enables protection to 'equivalents' beyond the literal scope of the claims,²⁰¹ the UK does not.

In the UK, claim scope is determined in accordance with the doctrine of 'purposive construction', well articulated for the first time in the famous *Catnic* decision²⁰² and reflected today in Article 69 of the EPC²⁰³ and the corresponding Protocol.²⁰⁴ In short, this approach entails the following:

- i) In construing a patent claim, as opposed to a strict literal interpretation, emphasis must be placed upon what the skilled person would have understood a patentee to mean by the language of the claims.
- ii) The issue of 'infringement' is a fairly straightforward assessment of whether the infringing product or process falls within the 'claim' scope, thus so purposively 'construed'.

²⁰¹ As per this doctrine 'a product or process that does not literally infringe upon the express terms of a patent claim may nonetheless be found to infringe if there is "equivalence" between the elements of the accused product or process and the claimed elements of the patented invention'. See *Graver Tank & Mfg. Co. v. Linde Air Products Co* 339 US 605, 70 S Ct 854 (1950). See also *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.* 520 US 17, 117 S Ct 1040 (1997) and more recently *Festo Corporation V Shoketsu Kinzoku Kogyo Kabushiki Co Ltd* 535 US 722, 122 S Ct 1831 (2002). The effect of the doctrine is to extend protection to equivalents outside the claims which perform substantially the same function in substantially the same way to obtain substantially the same result. See *Amgen (HL)* (n 187) [38].

²⁰² *Catnic Components Ltd v Hill & Smith Ltd* [1982] RPC 183, 243.

²⁰³ In *Amgen (HL)* (n 187) [48], Lord Hoffman categorically stated that the *Catnic* principle was precisely in accordance with Article 69 and the protocol. He also noted that '...since *Catnic*, the UK has had Article 69 which, firmly shuts the door on any doctrine which extends protection outside the claims.' *ibid* [44].

²⁰⁴ Protocol on the Interpretation of Article 69 of the Convention, adopted at the Munich Diplomatic Conference for the setting up of a European System for the Grant of Patents on 5 October 1973 (hereafter 'Protocol')

The hostility of English courts towards the 'doctrine of equivalents' was most recently witnessed in *Amgen*²⁰⁵ when Lord Hoffman expressed his anguish at this doctrine, owing to which 'American patent litigants pay dearly for results which are no more just or predictable than could be achieved by simply reading the claims.'²⁰⁶

Amgen articulates the UK position on the scope of patent claims in a succinct manner and is therefore a good starting point for a discussion in this regard. As noted earlier,²⁰⁷ *Amgen*, a California pharmaceutical company which held a patent on recombinant EPO for the treatment of anaemia, sued TKT for its gene-activated Erythropoietin product, GA-EPO. While in the UK, the legal outcome favoured TKT, the reverse situation prevailed in the US.²⁰⁸ I first consider the UK ruling before moving on to the US one.²⁰⁹

(i) Amgen: UK position

The House of Lords upheld the unanimous Court of Appeal decision that TKT's gene-activated erythropoietin (GA-EPO) product does not infringe Amgen's patent.²¹⁰ However it overruled the Court of Appeal on validity and held that two of the main claims were invalid. While the House of Lord's decision covers many interesting issues, including product-by-process claims, insufficiency, anticipation

²⁰⁵ *Amgen (HL)* (n 187).

²⁰⁶ *ibid* [44]. Lord Hoffman delivered the judgment, with which all the other Law Lords concurred.

²⁰⁷ See text after n 184.

²⁰⁸ It is to be noted that the US ruling is not a final one and could be subject to further appeals.

²⁰⁹ As with the rest of the paper, the focus will be on the UK position—however in order to appreciate this position, it is important that it be contrasted with the US position.

²¹⁰ *Amgen (HL)* (n 187). On 31 July 2002, the UK Court of Appeal, reversing the earlier decision of the Patents Court, ruled that the contentious claims were valid (claims 19 and 26), but that TKT does not infringe. See *Kirin-Amgen Inc v Transkaryotic Therapies Inc (No 2)* [2002] EWCA Civ 1096; [2003] RPC 3 (CA), which reversed in part the lower court decision in *Kirin-Amgen Inc v Transkaryotic Therapies Inc (No 2)* [2002] RPC 2 (Ch D (Patents Ct)).

and 'purposive construction', I will, for the purpose of our discussion here focus on the issue of 'purposive construction'.

The main issue was whether TKT's method of manufacturing EPO fell outside the claims of Amgen's patent. Lord Hoffman considered in detail the rules of construction appropriate to such a situation before proceeding to apply them to the facts. He emphasised that:

[T]he determination of the extent of protection conferred by a European patent is an examination in which there is only one compulsory question, namely that set by Article 69 and its Protocol: what would a person skilled in the art have understood the patentee to have used the language of the claim to mean?²¹¹

In an interesting twist, Lord Hoffman also warned that the three questions ('Protocol questions') which he himself had set out in *Improver v Remington*²¹² for determining scope were 'only guidelines' and were 'more useful in some cases than in others.'²¹³

²¹¹ *Amgen (HL)* (n 187) [69].

²¹² *Improver Corpn v Remington Consumer Products Ltd* [1990] FSR 181, 189. Since *Improver*, the Protocol Questions had been widely applied by the English Courts in order to determine whether equivalents fall within the scope of the claims and have become definitive of the approach of the English courts to the interpretation issue. In short, the questions were:

(1) Does the variant have a material effect upon the way the invention works? If yes, the variant is outside the claim. If no:

(2) Would this (i.e. that the variant had no material effect) have been obvious at the date of the publication of the patent to a reader skilled in the art? If no, the variant is outside the claim. If yes:

(3) Would the reader skilled in the art nevertheless have understood from the language of the claim that the patentee intended that strict compliance with the primary meaning was an essential requirement of the invention? If yes, the variant is outside the claim.

²¹³ *Amgen (HL)* (n 187) [52].

After laying down these rules of construction, Lord Hoffman moved on to apply them to the facts. Of the 31 claims in the patent,²¹⁴ only three were treated as relevant. These claims (1, 19 and 26) are briefly summarized as under:

- i) Claim 1: A DNA sequence for use in securing the expression of EPO in a host cell, such sequence selected from tables in the patent or related sequences;
- ii) Claim 19: EPO which is the product of the expression of an exogenous DNA sequence, and which has a higher molecular weight by the 'SDS-PAGE' testing method than existing EPO derived from extraction from urine; and
- iii) Claim 26: EPO which is the product of the expression in a host cell of a DNA sequence according to claim 1.

It must be noted at this juncture that the issue of infringement of the DNA sequence itself (claim 1) never arose directly as the alleged infringement was by importation of the EPO product—the subject matter of claims 19 and 26. However it did arise indirectly, since claim 26 referred back to claim 1.

The key issue in determining the scope of the patent was the construction of the term 'host cell' as used in claim 26 (and claim 1).²¹⁵ In order to resolve this issue, it is important to appreciate the difference underlying the two technologies. While Amgen's process for the manufacture of EPO relied on an exogenous DNA sequence coding for EPO (which was introduced into the host cell), the TKT method involved gene activation of an endogenous DNA sequence by an exogenous upstream control sequence.²¹⁶

²¹⁴ European Patent No 0148605B2. *Amgen (HL)* (n 187) [1].

²¹⁵ *Amgen (HL)* (n 187) [53].

²¹⁶ See text after n 185.

On the evidence, the House of Lords concluded that the skilled person would not regard TKT's process using an endogenous coding sequence to produce GA-EPO as involving a 'host cell', required by claim 1.²¹⁷ Consequently, TKT's GA-EPO was not an EPO falling within claim 26.

Similarly, the court held that GA-EPO was not 'the product of ... expression of an exogenous DNA sequence' within claim 19, and so there was no infringement under this claim as well.²¹⁸

Much in line with its principle of construction outlined earlier, the court made it abundantly clear that this is where the analysis should end. The claim had been construed 'purposively', and on the facts there was no infringement. It specifically disapproved of any further attempt to apply the Protocol questions over and above that construction.²¹⁹

²¹⁷ *Amgen (HL)* (n 187) [58], [80].

²¹⁸ *ibid* [58].

²¹⁹ *ibid* [70].

(ii) Amgen: US position

At the outset, it is important to note that the US and UK cases cannot be compared directly, as the claims in the patents were not exactly the same. Nonetheless, to the extent that they can be so compared, it would appear that the US courts did grant a much broader scope to Amgen's US patent than did the UK courts to the corresponding European patent.²²⁰

Illustratively, while the UK courts relied on the 'endogenous' versus 'exogenous' distinction in concluding that TKT's 'endogenous' process fell outside Amgen's claim scope, the US courts did not want to read in such a limitation into Amgen's claim.²²¹ The Court of Appeal articulated the position thus:²²²

Guided by our principles of claim construction, we agree with the district court that TKT improperly seeks to import the "exogenous" limitation into the claims. The plain meaning of the claims controls here, and they plainly are not so limited. The statement that the invention is "uniquely characterized" by the expression of exogenous

²²⁰ 'The patent claims at issue in the US are not directly comparable to those in the European patent'. See J Nurton 'Lords Reject Equivalents Test' *Managing Intellectual Property (MIP)* <<http://www.legalmediagroup.com>> (3 December 2004).

²²¹ The case began brewing in 1997 when a declaratory suit was filed by Amgen against TKT and Hoechst Marion Roussel (collectively referred to as TKT). A District Court in Boston ruled that three of the main patents of Amgen were valid and infringed by TKT. See *Amgen Inc v Hoechst Marion Roussel Inc* 126 F Supp 2d 69 (Mass 2001) (hereafter 'Amgen (US I)'). On appeal by TKT, the Federal Circuit affirmed a majority of the lower courts findings but vacated and remanded a few issues, relating to the validity of two product patents on EPO and the validity and infringement of two patents with claims to EPO producing cells and methods for producing EPO. See *Amgen Inc v Hoechst Marion Roussel Inc* 314 F 3d 1313 (Fed Cir 2003) (hereafter 'Amgen (US II)'). The District Court recently addressed these issues on remand. *Amgen v Hoechst Marion Roussel Inc* 339 F Supp 2d 202 (Mass 2004) ('Amgen (US III)'). The ultimate result of this decision, coupled with the District Courts' earlier decisions, is that the four Amgen patents at issue have been held valid, enforceable, and infringed by TKT.

²²² *Amgen (US II)* (n 221) 1326.

DNA sequences does not impel us to accept TKT's position when the asserted claims do not contain such an express limitation.

Similarly, despite differences in Amgen's EPO product and TKT's GA-EPO, the doctrine of equivalents was applied to find in favour of Amgen. Although TKT was found to not 'literally' infringe the '080 patent,²²³ since TKT's product 'performed substantially the same function in substantially the same way to obtain substantially the same result' as the 166-amino acid EPO, it was found to be infringing under the doctrine of equivalents.²²⁴

A broad comparison between the US and UK positions demonstrates that not only is the process of assessing legal viability a rather complex one but also that the results of such assessment would vary from jurisdiction to jurisdiction.

(b) Research Exemption

As mentioned earlier, apart from determining 'scope', a legal viability analysis would include investigating other factors such as the scope of the research exemption.

Even assuming that an alternative to a patented gene does not fall within the scope of the patent, it is still possible that the very process of creating that alternative or substitute infringes. This is particularly so in situations where one

²²³ In April 1997, when Amgen initially filed against TKT for a declaratory judgment of infringement, three patents were at issue, including the '080 patent. However in October 1999, Amgen amended its complaint to include infringement of two additional patents that were issued after the initial complaint.

²²⁴ *Amgen (US I)* (n 221) 186-87.

cannot create the substitute without working 'with' the patented gene in question.²²⁵

This is where a robust 'research exemption' helps. As already mentioned in Chapter III, such 'research exemption' exists in most patent regimes and is an important tool that guarantees a certain amount of flexibility in using the patented invention whilst working towards a downstream product. Unfortunately, as shown in that chapter, the scope of this exemption is limited, particularly in the context of those gene patents that qualify as 'research tool' patents.²²⁶

2 Technical Viability

After having determined that the alternative or substitute is legally viable, one ought to assess its technical viability. As stated in Chapter IV, in the context of alternatives to patented genes, the key issue is whether one could expect broadly similar results when working with the substitute. The Walsh et al paper cited one such concern expressed by a representative from a pharmaceutical firm:

Because there is a patent on the human gene, you work with the guinea pig gene, but it is not the best approach. That's very frustrating. In a number of cases, we can't work with this protein or this gene and it slows things down.²²⁷

²²⁵ Such infringements are however difficult to detect. See Walsh et al (n 7), which stated that this non detection formed part of the repertoire of working solutions. See text to n 52.

²²⁶ See text after n 88.

²²⁷ Walsh (n 7) 314.

Similarly, although substituting the gene of a nematode worm or a chimpanzee for the patented human BRCA gene, (as proposed in Chapter IV) could work for researchers trying to define the function of the corresponding protein, they may not be of much help in the context of a clinical test that has a direct and immediate use for patients.²²⁸

3 Economic Viability

If the alternative in question passes the above two thresholds, it has still to clear the 'economic viability' hurdle—perhaps the most complex one in the context of a viability assessment. As stated earlier, 'economic viability' would involve consideration of factors that are less definite than those pertaining to a legal or technical viability analysis.²²⁹

Given the high R&D costs inherent in any biopharmaceutical research, one of the more definite factors to take into consideration could be the 'financial viability' of an alternative.²³⁰ Thus for example, President Bush's decision to deny federal funding to human embryonic cell lines created after 9 August 2001²³¹ limited the ability of researchers to procure finance and thereby to invent around WARF's patents over stem cells.²³²

²²⁸ Arupa Ganguly (Asst Professor, Dept of Genetics, University of Pennsylvania) <ganguly@mail.med.upenn.edu> email (2 January 2004). Dr Ganguly's lab was one amongst the many that had to discontinue diagnostic testing for breast cancer owing to Myriads patents covering the breast cancer genes and diagnostic testing methods. See n 40.

²²⁹ Text after n 168.

²³⁰ 'Economic viability has two aspects: financial, which measures the chances of acquiring financing for a project (often, but not always related to the amount of capital required), and efficiency'. See Wolf and Murakami (n 172) 151.

²³¹ On August 9, 2001, President George W. Bush announced that federal funding for stem cell research would be limited to the then-existing stem cell lines. See n 47.

²³² As noted earlier (n 47), this patent held by Wisconsin Alumni Research Foundation (WARF) covering pluripotent embryonic stem cells (and the method for isolating them) were exclusively licensed to Geron Corporation for the commercial development of a number of cell types.

Similarly, as mentioned earlier in this chapter, Synergene, a Maltese company that had been circumventing Myriad's patents by performing breast cancer tests in Malta decided to discontinue it on what appears to be 'economic' grounds.²³³

C COMPLEXITY OF THE 'ESSENTIALITY' ANALYSIS

As evident from the above discussion, the process of evaluating 'essentiality' is a fairly complex process. Indeed, one might even question the 'viability' of such an assessment. Would a competition authority have the necessary expertise/resources to undertake this investigation, in all its complexity?²³⁴

At least, to the extent of determining the scope of an intellectual property right, a ruling by an intellectual property authority or court on this issue would help. In fact, most cases where the doctrine of essential facilities is invoked also involve parallel infringement proceedings before the courts (as was the case with *IMS* and *Magill*).²³⁵ However, as *IMS* more than amply illustrates, there can be problems with such reliance. The Commission's interim ruling that the facility was an 'essential' one was based substantially on the ruling by a German court that competing brick structures had infringed IMS's copyright over the 1860 brick structure. This ruling was later modified by an appellate court, which

²³³ 'BRCA testing is very resource intensive and hence it was decided to dedicate such resources to alternative projects.' Kevin Camilleri (Operations Director, Synergene Biotechnology Group Malta) <kevinc@synergene.net> email (5 November 2004).

²³⁴ Here again, time and space constraints prevent me from reflecting in greater detail on the level of complexity involved and how best an authority can simplify this analysis. However, I will attempt to extract the key issues that such a discussion would entail.

²³⁵ See also *Intel* (n 158), a UK patent infringement law suit where the defendant raised Article 81 and 82 defences (commonly labelled 'Euro Defences'). A split trial of the patent law and the competition law aspects of the case was ordered. The trial judge favoured Intel's application for summary disposal of the Euro Defences on the ground that they had no real prospect of success. See A Toutoungi *Intel V Via: Holding Back The Tide Of Compulsory Licensing* (2002) 24 (11) EIPR 548. The Court of Appeal however overruled the initial decision and reinstated all of Via's Eurodefences. The matter was subsequently settled.

restricted the scope of IMS's copyright and seemed to suggest that some alternative brick structures would be non-infringing. Consequently, the Commission was forced to withdraw its interim ruling.²³⁶

Should a competition authority therefore necessarily have to wait for a final ruling on the scope of intellectual property before applying the essential facilities doctrine? This may not be an efficient outcome, particularly in cases where the abusive practice in question could have harmed the competitive structure of the market considerably in the interim. Also, what of those cases where there is no such parallel proceeding before an intellectual property tribunal or court?

There are ways to mitigate this complexity and one such solution is found in the Commission's approach in IMS. As noted earlier, the Commission categorised 'substitutes' to the 1860 brick structure as 'legally uncertain'²³⁷ and therefore 'legally non viable'. Without delving extensively into the merits of the copyright dispute, the Commission made some assumptions for the purpose of its analysis:

The Commission assumes for the purpose of these proceedings and according to German law that the 1860-brick structure is covered by a copyright. This legal assessment will not consider questions of copyright law either with regard to the specific subject matter of the right or the national measures which the German court employs to enforce copyright legislation. The Commission notes that the Frankfurt Court considered that the

²³⁶ Text after n 163.

²³⁷ *ibid.* See also *IMS I* (n 68) [143]-[145].

1860 brick structure is a database, and that copyright protection for databases is harmonised under Directive 96/9/EC.²³⁸

Drawing from the *IMS* experience therefore, one ought not to shy away from engaging in a meaningful way with an assessment of essentiality. Rather, some complexities could be resolved by relegating borderline cases to the category of 'legally' non-viable—as any substitute would be 'legally uncertain'.

²³⁸ *IMS I* (n 68) [36].

CHAPTER VI

CONCLUSION

*'A knot!' said Alice, always ready to make herself useful, and looking anxiously about her. 'Oh, do let me help to undo it!'*²³⁹

I began this journey by exploring the doctrine of essential facilities as a potential solution to the 'knotty' issue of the blocking impasse in the biopharmaceutical arena. However in the process, an even knottier issue arose—whether patented genes were 'essential facilities' in the first place. Without in any way claiming to have un-knotted this conundrum (if at all that were possible), I do hope I have provided a robust enough framework to determine 'essentiality' on a case-by-case basis. No doubt, patented genes are very difficult to invent around—however, as this paper has shown, despite this 'difficulty' in 'inventing around', not all patented genes are absolutely 'essential' in the competition law sense.

Paradoxically, the very application of the essential facilities doctrine and an assessment of the 'essentiality' limb in particular could help determine the existence and extent of blocking. Recent empirical studies note that the perceived problems of blocking have been mitigated to a large extent by certain working solutions adopted by the industry, one of which is the ability to 'invent around'.²⁴⁰ In other words, if the facility is a non-essential one, then there can be no 'blocking' or 'restricted access'. However the converse need not always be true—if the facility is an essential one, but is widely licensed, it is quite possible that there would be no 'blocking'. Applying the essentiality framework therefore

²³⁹ L Carroll *Alice in Wonderland* (Illustrated by Sir John Tenniel) eBooks@Adelaide (University of Adelaide South Australia 2004) <<http://etext.library.adelaide.edu.au/c/carroll/lewis/alice/chapter3.html>> (2 Jan 2005).

²⁴⁰ See Walsh et al (n 7), OECD Report (n 8) and Nielsen (n 8).

to specific cases of patented genes, one could generate data that could then be used to determine the extent of blocking or restricted access. This could in turn help decide whether the 'blocking' is of such a widespread nature as to warrant a substantial legal and/or institutional response.

In this regard, it is pertinent to note that a competition law remedy cannot be a panacea to resolve the blocking or restricted access issue for all time to come. Rather, if the blocking issue becomes pervasive, it may be more prudent to devise a more focussed remedy. However until such time as this issue reaches such proportion, the 'essential facilities doctrine' holds promise as a robust solution. Needless to say, this preliminary conclusion can only be validated after one has explored other aspects (limbs) of the doctrine. And with that in mind, it is now time to break this journey.

