

BLOCK ME NOT: HOW “ESSENTIAL” ARE PATENTED GENES?

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I. INTRODUCTION

A thousand-mile journey begins with a single step.
—Lao Tzu¹

The biopharmaceutical² industry is characterized by the “cumulative innovation” paradigm, wherein the discovery of a gene³ sequence is only the first step. In order to convert such sequence information into viable products, tests, and cures for genetic conditions and diseases, much additional time, effort, and money must be spent.⁴ 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.⁵

My journey began as an earnest attempt to find an effective solution to the blocking impasse referred to above. Early in this endeavor,

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1. LAO TZU, TAO TE CHING 73 (David Hinton trans., Counterpoint Press 2000) (n.d.).

2. A “biopharmaceutical” is defined broadly as “any biology-based therapeutic that structurally mimics compounds found within the body. This includes recombinant proteins, monoclonal and polyclonal antibodies, peptides, antisense oligonucleotides, therapeutic genes, and certain therapeutic vaccines.” Paul C. Nagle et al., *Defining and Characterizing the Late-Stage Biopharmaceutical Pipeline*, 9 AM. J. MANAGED CARE S124 (2003). However, in this Article, I use this term primarily in relation to “therapeutic genes” and their resulting products.

3. 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.” DAVID SUZUKI & PETER KNUDTSON, *GENETHICS* 343 (Harvard Univ. Press 1990).

4. Jean Lanjouw describes the cumulative nature of the innovation process: “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.” Jean O. Lanjouw, *A Discussion of “Of Patents and Genes: Flows of Knowledge and Intellectual Property Rights”* by Claude Henry, Remarks at the World Bank ABCDE Conference 3 (May 16, 2003), available at [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).

5. *Id.* at 3–4.

realization struck that the journey was beset with multiple pathways and that not even one of them could be traversed successfully within the course of one paper. Caught at the crossroads of these daunting multiple pathways, it struck me that, before beginning to explore remedies to this problem, I ought to question the basic assumption that patented genes necessarily blocked downstream research.

A. *The Journey Begins: An Explanation of the Title*

To begin, 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 shrinks and withdraws into itself upon any kind of touch—hence the name.⁶ In much the same way as this plant, gene patents are a highly sensitive issue that, unless handled with appropriate delicacy, could have fatal ramifications for biomedical drug discovery. In this regard, it bears noting that this Article will focus largely on patents covering therapeutic genes because the cumulative structure of the biopharmaceutical industry is more pronounced in this context.⁷

The change from “touch” to “block” in the title reflects 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 Article to include not only “blocking patents,”⁸ but also all instances where downstream research is blocked by patents on upstream inventions.⁹ A paper by Professor John P. Walsh and others refers to this as the “restricted access” issue.¹⁰ For the sake of convenience, therefore, I will refer to this phenomenon as the “blocking” or “restricted access” issue.

This blocking or restricted access issue has been the subject of several important papers¹¹ that suggest a wide array of solutions, ranging

6. See, e.g., JOHN K. FRANCIS, U.S. DEP'T OF AGRICULTURE, *MIMOSA PUDICA* L. 1 (2003), available at <http://www.fs.fed.us/global/iitt/pdf/shrubs/Mimosa%20pudica.pdf>.

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

8. 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 license from the holder of the dominant patent and vice versa. See Robert Merges, *Intellectual Property Rights and Bargaining Breakdown: The Case of Blocking Patents*, 62 TENN. L. REV. 75, 81–82 (1994).

9. See Olufunmilayo Arewa, *Blocking, Tackling and Holding: Boundaries, Marking and Strategic Business Uses of Intangibles* (Case W. Reserve Univ. Sch. of Law, Case Legal Studies Research Paper No. 04-13, 2004), available at <http://ssrn.com/abstract=586483> (using 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”).

10. John P. Walsh et al., *Effects of Research Tool Patents and Licensing on Biomedical Innovation*, in PATENTS IN THE KNOWLEDGE-BASED ECONOMY 285, 286 (Wesley M. Cohen & Stephen A. Merrill eds., 2003).

11. Professor Merges, as well as several others, have dealt with the blocking issue in some of their papers. See Merges, *supra* note 8; Robert P. Merges & Richard R. Nelson, *On the Complex*

from remedies within patent law (for example, compulsory licensing of the patent or a wider research exemption) to remedies in other legal disciplines such as antitrust law.¹²

However, my focus will be in taking a step backwards and questioning the theoretical assumption that there is a blocking or restricted access issue in the biopharmaceutical industry. This assumption is premised on the arguments that one cannot invent around patented genes and that there are no viable substitutes for such genes.¹³ Therefore, I will investigate the merits of such arguments by asking, "How essential is a patented gene?" If the patented gene is not absolutely essential for use by a downstream researcher, in that there are substitutes available to work with or ways in which the patent in question could be circumvented, clearly the patented gene will not block the downstream researcher. In this sense, while the first part of the title, "Block Me Not," expresses the blocking concern in general (the thousand-mile journey), the latter part, "How 'Essential' Are Patented Genes?," is the more specific question that this Article seeks to address (the first step in this long and arduous journey).

B. Structure

This Article proceeds as follows. Part II discusses the blocking or restricted access issue, using the HIV gene (CCR5) and the breast cancer gene (BRCA1 and BRCA2) as specific examples. Part III deliberates on the doctrine of essential facilities and draws out a framework for determining "essentiality." Part IV discusses the availability of substitutes or alternatives to patented genes and, in the process, questions the widely held assumption that one cannot invent around patented genes. Part IV uses the essentiality framework as a tool to assess the viability of substitutes or alternatives to patented genes, yielding interesting insights in the process.

Economics of Patent Scope, 90 COLUM. L. REV. 839 (1990); see also NUFFIELD COUNCIL ON BIOETHICS, THE ETHICS OF PATENTING DNA (2002), available at <http://www.nuffieldbioethics.org/fileLibrary/pdf/theethicsofpatentingdna.pdf> [hereinafter NUFFIELD PAPER] (focusing on the United Kingdom's position); ORG. FOR ECON. CO-OPERATION & DEV., GENETIC INVENTIONS, INTELLECTUAL PROPERTY RIGHTS AND LICENSING PRACTICES 77 (2002), available at <http://www.oecd.org/dataoecd/42/21/2491084.pdf> [hereinafter OECD REPORT] (specifically referring to blocking in the context of biotechnology or biopharmaceuticals); JOSEPH STRAUS ET AL., MAX PLANCK INST. FOR INTELLECTUAL PROP., COMPETITION & TAX LAW, GENETIC INVENTIONS AND PATENT LAW: AN EMPIRICAL SURVEY OF SELECTED GERMAN R & D INSTITUTIONS (2004) (providing an empirical study in the German context); Walsh et al., *supra* note 10 (focusing on the United States); Dianne Nicol & Jane Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (Centre for Law and Genetics, Occasional Paper No. 6, 2003), available at <http://www.law.unimelb.edu.au/ipria/publications/workingpapers/BiotechReportFinal.pdf> (providing an empirical study in the Australian context).

12. See *Merges*, *supra* note 8, at 91.

13. OECD REPORT, *supra* note 11, at 11.

II. GENE PATENTS: THE “BLOCKING” OR “RESTRICTED ACCESS” ISSUE

*If it ain't broke, don't fix it.*¹⁴

The prospect of downstream inventions being blocked by broad upstream patents¹⁵ is not merely anecdotal but has some historical basis. In a groundbreaking paper, Merges and Nelson demonstrated that, in a variety of industries, broad upstream patents hindered further development of the technology.¹⁶ Thus, for example, in the field of incandescent lighting, Thomas Edison's broad patent was used to shut down competitors' improvements.¹⁷

A. Blocking in the Biopharmaceutical Industry

For several reasons, the biopharmaceutical industry seems an ideal arena for blocking problems to occur. First, patents have been granted at the initial stages of gene sequencing to DNA sequences with no known function other than their mere use as probes.¹⁸ Quite apart from the fact that these grants were seen as unfair,¹⁹ inherent in these grants was the potential for blocking any further research using the patented sequences.²⁰ To appreciate the magnitude of this issue, consider that, by 2002, the total number of patents on genes and genetic material granted by the United States Patent and Trademark Office (USPTO) alone was estimated to be around 8000, of which about 1500 covered human genetic

14. This phrase is popularly attributed to Bert Lance, Director of the Office of Management and Budget under President Carter, though it is most likely much older. See *Emphasizing the M in OMB, NATION'S BUS.*, May 1977, at 27, 27.

15. Professor Rai uses the terms “upstream” and “downstream” to “identify the proximity (temporal and conceptual) of particular research to a particular end product.” Arti K. Rai, *Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and Antitrust*, 16 *BERKELEY TECH. L.J.* 813, 816 n.9 (2001). However, she emphasizes “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.’” *Id.*

16. Merges & Nelson, *supra* note 11, at 908–09.

17. “More importantly for our purposes, the validation of Edison's broad patent slowed down the pace of improvements considerably.” *Id.* at 886.

18. Shammad Basheer, *Patenting Genes and Gene Sequences: The Next El Dorado* 16 (2001) (unpublished manuscript, available at <http://users.ox.ac.uk/~edip/basheer.pdf>). Probes are short pieces of DNA that can be used to probe or explore a sample of DNA for its complementary piece. *Id.* at 16 n.66.

19. 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, *supra* note 4, at 6. There is a tendency to treat the blocking issue in tandem with the “fairness” issue. The immediate focus of this Article, however, will be on remedying a blocking situation without delving into the issue of whether the patents that block are fair. It may be the case that the level of fairness could influence the outcome when applying the competition law remedy that is advocated in this Article; however, time and space constraints compel me to omit that discussion.

20. Lori Andrews, *The Gene Patent Dilemma: Balancing Commercial Incentives with Health Needs*, 2 *HOUS. J. HEALTH L. & POL'Y* 65, 79–81 (2002).

material.²¹ Similarly, about 605 patent applications pertaining to human or animal DNA sequences were filed at the European Patent Office in 2000.²²

Second, 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 them.²⁴ Because of these factors, gene patents “grant real monopolistic power in a market already fraught with inefficiencies.”²⁵

Third, 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, which includes thyroid cancer, and Hirschsprung disease, a disorder of the intestinal tract.²⁶ As commentators have noted, “A single patent over the sequence would give the patent holder potential control over two very different disorders.”²⁷ Most patent regimes stipulate that a patent over a novel product entitles the patentee not only to the use identified in the patent application but to all its uses, even those that that may be discovered in the future by third parties.²⁸

Fourth, multiple patents over such gene sequences also could result in what Heller and Eisenberg refer to as the “tragedy of the anticommons”—a situation where there are numerous property rights

21. 107 CONG. REC. E353 (daily ed. Mar. 14, 2002) (statement of Rep. Rivers), available at http://frwebgate.access.gpo.gov/cgi-bin/getpage.cgi?dbname=2002_record&page=E353&position=all; see also OECD REPORT, *supra* note 11, at 34.

22. OECD REPORT, *supra* note 11, at 8.

23. It was thought initially that the human genome contained about 27,000 to 40,000 genes; recent research, however, has reduced this figure to a mere 20,000 to 25,000 genes. See Andy Coghlan, *Recount Slashes Number of Human Genes*, NEWSIDENTIST.COM, Oct. 20, 2004, <http://www.newscientist.com/article.ns?id=dn6561>.

24. See Andrews, *supra* note 20, at 78–79; Gert Matthijs & Dicky Halley, *European-wide Opposition Against the Breast Cancer Gene Patents*, 10 EUR. J. HUM. GENETICS 783, 784 (2002); see also Lorelei Perez Westin, *Genetic Patents: Gatekeeper to the Promised Cures*, 25 T. JEFFERSON L. REV. 271, 297 (2002) (stating that “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. *Gene Patents and Other Genomic Inventions: Oversight Hearing Before the Subcomm. on Courts and Intellectual Property of the H. Comm. on the Judiciary*, 106th Cong. 124–28 (2000) (statement of Jon F. Merz, Assistant Professor, University of Pennsylvania).

26. W.R. CORNISH ET AL., INTELLECTUAL PROPERTY RIGHTS (IPRS) AND GENETICS: A STUDY INTO THE IMPACT AND MANAGEMENT OF INTELLECTUAL PROPERTY RIGHTS WITHIN THE HEALTHCARE SECTOR 32 (2003), available at http://www.phgu.org.uk/about_phgu/resources/word/s-ipr1.doc; see also U.S. National Library of Medicine, RET—Genetics Home Reference, <http://ghr.nlm.nih.gov/gene=ret> (last visited Nov. 28, 2005). The underlying RET mutations are so different that “these two disorders rarely occur in the same individual.” U.S. National Library of Medicine, RET—Genetics Home Reference, *supra*.

27. W.R. CORNISH ET AL., *supra* note 26, at 32.

28. See NUFFIELD PAPER, *supra* note 11, paras. 5.58, .61. “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.” *Id.* para. 5.61.

claims over the building blocks necessary for research and development.²⁹ 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.³⁰ In contrast to the prospect of an anticommons, 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.³¹ Needless to say, the focus of this Article will be on the blocking or restricted access issue.

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

1. CCR5 Patent

In 2000, the USPTO granted a patent to Human Genome Sciences, Inc. (HGS), covering the gene sequence of the CCR5 receptor.³² This receptor is a protein³³ 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.³⁴ However, the HGS patent application did not mention a utility in HIV research.³⁵ Rather, the application defined the utility of the invention as, among other things, a tool for screening for receptor agonists and antagonists and as a diagnostic tool for detecting mutations in the gene itself.³⁶

29. Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 698 (1998).

30. *Id.*

31. Interestingly, in a later paper, co-authored with Professor Rai, Professor Eisenberg states as follows:

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.

Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289, 297 n.46 (2003), available at <http://www.law.duke.edu/journals/66LCP Rai>.

32. U.S. Patent No. 6,025,154 (filed June 6, 1995) (issued Feb. 15, 2000).

33. 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. See HUTCHINSON DICTIONARY OF SCIENCE 265 (1997). Proteins serve essential functions in the human body. *Id.* Illustratively, they regulate metabolism (enzymes); make up skin, bones, and ligaments (keratin and collagen); produce movement (muscle proteins); transport oxygen (hemoglobin); and regulate movement of substances into and out of cells (membrane proteins). *Id.*

34. Nelson L. Michael et al., *The Role of CCR5 and CCR2 Polymorphisms in HIV-1 Transmission and Disease Progression*, 3 NATURE MED. 1160, 1160 (1997).

35. Eliot Marshall, *Gene Patents: Patent on HIV Receptor Provokes an Outcry*, 287 SCIENCE 1375, 1377 (2000).

36. HGS filed its patent application for the CCR5 gene as a so-called "homologous sequence," which is a gene sequence of unknown utility, the biological function of which could be predicted because it was similar to a separate sequence with function that already had been identified. David Dickson, *NIH Opposes Plans for Patenting 'Similar' Gene Sequences*, NATURE, May 4, 2000, at 3.

Other researchers, such as Professor Marc Parmentier, subsequently discovered that the CCR5 receptor was the “docking receptor” used by the HIV virus to infect a cell.³⁷ 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.³⁸ 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.³⁹

2. *BRCA Patents*

In another controversial example, Myriad Genetics (“Myriad”), a U.S. corporation, was accused of stifling research by demanding excessive royalties for patents covering the breast cancer genes, BRCA1 and BRCA2.⁴⁰ It was feared that Myriad’s actions would prevent the emergence of new and improved tests for diagnosing breast cancer.⁴¹ 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 (meaning no mutations detected) when tested by Myriad.⁴² This indicated that Myriad’s tests were far from perfect and that Myriad’s approach to testing, which involved full DNA sequencing of the two BRCA genes, could detect only small-scale deletions and rearrangements.⁴³ Myriad’s patents, however, ensured that the company could stunt the emergence of any other tests.⁴⁴

Researchers often use this process of identification. *Id.*; see also Martin Enserink, *Biomedical Patents: Patent Office May Raise the Bar on Gene Claims*, 287 SCIENCE 1196, 1197 (2000).

37. The USPTO recently granted a patent in this regard to Euroscreen s.a., a Belgian company that Parmentier founded. Press Release, Euroscreen, Euroscreen Awarded US Patent Covering Key HIV Target (Oct. 9, 2002), available at <http://www.euroscreen.be/index.cfm?act=dspNews&id=135&l=1>.

38. Marshall, *supra* note 35, at 1377.

39. *See id.*

40. Currently, Myriad holds approximately twenty patents worldwide covering the BRCA1 and BRCA2 genes, certain mutations of the genes, and tests to detect mutations in these genes. Jordan Paradise, *European Opposition to Exclusive Control Over Predictive Breast Cancer Testing and the Inherent Implications for U.S. Patent Law and Public Policy: A Case Study of the Myriad Genetics’ BRCA Patent Controversy*, 59 FOOD & DRUG L.J. 133, 136–37 (2004).

41. 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 S.J.R. Bostyn, *The Prodigal Son: The Relationship Between Patent Law and Health Care*, 11 MED. L. REV. 67, 106 (2003).

42. Bryn Williams-Jones, *History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing*, 10 HEALTH L.J. 123, 139 (2002).

43. *Id.*

44. The lab of Arupa Ganguly, a geneticist at the University of Pennsylvania, was stopped from testing despite the fact that its tests were believed to be more accurate and cheaper than those of Myriad and the fact that some of the testing was done for research purposes. Julian Borger, *Rush to*

As with CCR5, a variety of factors mitigated the blocking or restricted-access threat of the BRCA patents. For example, the recent grant of a European patent covering the BRCA2 gene to an English charity (Cancer Research U.K.) has diminished the impact of Myriad's monopoly over the breast cancer genes.⁴⁵ This charity has committed to granting royalty-free licenses to public laboratories throughout Europe.⁴⁶ 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 on grounds of lack of novelty.⁴⁷ This development further reduces the impact of Myriad's monopoly.

B. Walsh et al. Paper and "Working Solutions"

The fact that external circumstances or, as with CCR5, the parties' own conduct mitigated blocking concerns in the above cases leads to speculation that there 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,⁴⁸ in which 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 licenses, inventing around patents, infringement (often informally invoking a research exemption), developing and using public tools, and challenging patents in court."⁴⁹ A 2002 report by the Organisation for Economic Co-operation and Development (OECD) broadly reflected these conclusions, stating that "[t]he 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."⁵⁰

Patent Genes Stalls Cures for Disease, GUARDIAN, Dec. 15, 1999, at 1, available at <http://www.guardian.co.uk/Archive/Article/0,4273,3941983,00.html>.

45. The patent covers all attempts to sequence the gene or to test for damaged and inactive variants. Susan Mayor, *Charity Wins BRCA2 Patent: Genetics Researchers Welcome a Decision that Will Make the Gene Freely Available in Europe*, SCIENTIST, Feb. 13, 2004, <http://www.the-scientist.com/news/20040213/02>.

46. *Id.*

47. 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. Stéphanie Bodoni, *EPO Revokes Myriad Cancer Test Patent*, MANAGING INTELL. PROP., June 2004, at 6, 6, available at <http://www.managingip.com/default.asp?Page=9&PUBid=198&ISS=13072&SID=484586>.

48. Walsh et al., *supra* note 10. This paper dealt with whether the prospect of an anticommons, as feared by Heller and Eisenberg, had been realized and 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.

49. *Id.* at 286.

50. OECD REPORT, *supra* note 11, at 77. This report resulted from a workshop, held by the OECD Working Party on Biotechnology on January 24–25, 2002, in which several experts, including

These conclusions force us to question the assumption that there is a blocking or restricted access issue in the biopharmaceutical field. If there is none, we do not need to look for remedies or ways of tackling it. Because the blocking assumption is largely premised on the argument that there are no substitutes for patented genes, a good starting point in determining the existence and impact of blocking will be to ask whether viable substitutes to such patented genes exist, such that a downstream researcher could use these substitutes instead. Computing viability, however, is a difficult task, and it may, therefore, help to draw out a framework for doing so from a competition law concept, namely the doctrine of essential facilities.

III. THE ESSENTIAL FACILITIES DOCTRINE: A FRAMEWORK FOR ASSESSING ESSENTIALITY OR INDISPENSABILITY

With me everything turns into mathematics.
—René Descartes⁵¹

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 been met with a particularly warm welcome.

A. U.S. Origins of the Doctrine

The essential facilities doctrine originated in the United States and has been most widely applied in regulating access to physical infrastructure such as transport facilities⁵² and utility networks.⁵³ Advocate General Jacobs summarized the U.S. position as follows:

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 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

Dr. Straus and Dr. Walsh, presented their findings. *Id.* at 3, 45.

51. *E.g.*, George David Birkhoff, *Intuition, Reason and Faith in Science*, in *MUSINGS OF THE MASTERS: AN ANTHOLOGY OF MATHEMATICAL REFLECTIONS* 95, 110 (Raymond G. Ayoub ed., 2004).

52. *See generally* United States v. Terminal R.R. Ass'n of St. Louis, 224 U.S. 383 (1912) (pertaining to railroad bridges serving St. Louis, Missouri).

53. *See generally* Otter Tail Power Co. v. United States, 410 U.S. 366 (1973) (discussing the essential facility of a local electricity network); MCI Commc'ns Corp. v. Am. Tel. & Tel. Co., 708 F.2d 1081 (7th Cir. 1983) (ordering a local telecommunications network to provide access to its facility).

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.⁵⁴

With the U.S. Supreme Court's recent expression of hostility towards this doctrine in a case against Verizon Communications,⁵⁵ the extent of applicability of this doctrine in the United States is not clear.⁵⁶ However, the doctrine has gained prominence in Europe,⁵⁷ with the European Court of Justice (ECJ) delivering a much-awaited decision in 2004.⁵⁸

B. Emergence and Evolution of the Doctrine in Europe

1. European Community Treaty

In Europe, the essential facilities doctrine derives from Article 82 of the Treaty Establishing the European Community, which prohibits the abuse of a dominant position.⁵⁹ This article provides:

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 in so far as it may affect trade between Member States.

54. Case C-7/97, *Oscar Bronner GmbH v. Mediaprint Zeitungs- und Zeitschriftenverlag GmbH*, 1998 E.C.R. I-7791, Opinion of Advocate Gen., para. 47 (citations omitted).

55. *Verizon Commc'ns, Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 411 (2004). This case dealt with a complaint against a local telephone monopolist that had refused to deal with its rivals. *Id.* at 398. The 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." *Id.* at 411. The Court reasoned 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." *Id.*

56. Legal scholars in the United States have also been critical of this doctrine, particularly in its application to intellectual property. See Abbott B. Lipsky, Jr. & J. Gregory Sidak, *Essential Facilities*, 51 STAN. L. REV. 1187, 1187 (1999). More recently, see Herbert Hovenkamp et al., *Unilateral Refusals to License in the U.S.*, in ANTITRUST, PATENTS AND COPYRIGHT: EU AND US PERSPECTIVES 13, 23 (Francois Lévêque & Howard Shelanski eds., 2005), available at <http://ssrn.com/abstract=703161> ("We believe the better view is that an intellectual property right itself cannot constitute an essential facility, and that the doctrine should not be applied to cases that seek access to an intellectual property right in any but the most unusual of circumstances.").

57. John Temple Lang, *Defining Legitimate Competition: Companies' Duties to Supply Competitors and Access to Essential Facilities*, 18 FORDHAM INT'L L.J. 437, 439 (1994).

58. See Case C-418/01, *IMS Health GmbH v. NDC Health GmbH*, 2004 E.C.R. I-5039.

59. Consolidated Versions of the Treaty on European Union and of the Treaty Establishing the European Community, Dec. 24, 2002, 2002 O.J. (C 325) 1, 65 (providing the current Article 82 of the Treaty Establishing the European Community ("E.C. Treaty")). Earlier amendments to the E.C. Treaty significantly renumbered the articles, changing Article 86 to Article 82; thus, this discussion will refer only to Article 82. See Article 82 of the E.C. Treaty (ex Article 86), http://europa.eu.int/comm/competition/legislation/treaties/ec/art82_en.html (last visited Nov. 23, 2005).

Such abuse may, in particular, consist in:

(a) directly or indirectly imposing unfair purchase or selling prices or other unfair 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.⁶⁰

Article 82 thus requires an abusive act⁶¹ by a “dominant”⁶² undertaking within the European Community or in a substantial part of the European Community in a manner that actually or potentially affects trade between Member States.⁶³

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. In certain circumstances, a refusal to provide access to an essential facility could be tantamount to an abuse.

2. Case Law

An examination of case law 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 European courts have never expressly used the term “essential facilities doctrine.”⁶⁴ 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*

60. *Id.*

61. See Joined Cases C-395/96P & C-396/96P, *Compagnie Mar. Belge Transps. SA v. Comm'n*, 2000 E.C.R. I-1365, Judgment of the Court, para. 112 (holding that the list proposed in Article 86 [now Article 82] is not exhaustive).

62. 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 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 & Co. v. Comm'n*, 1979 E.C.R. 461, Judgment of the Court, para. 4.

63. See Joined Cases 6 & 7/73, *Istituto Chemioterapico Italiano SpA v. Comm'n (Commercial Solvents)*, 1974 E.C.R. 223, Judgment of the Court, para. 32 (holding that conduct could affect interstate trade when it altered the competitive structure of the market).

64. See Merges & Nelson, *supra* note 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* . . .” David Aitman & Alison Jones, *Competition Law and Copyright: Has the Copyright Owner Lost the Ability to Control His Copyright*, 26 EUR. INTELL. PROP. REV. 137, 138 n.11 (2004). The European Commission (the “Commission”), however, has referred to the essential facilities doctrine in some of its decisions, beginning with Commission Decision 94/19, *Sea Containers v. Stena Sealink*, 1994 O.J. (L 15) 8, 16.

Solvents.⁶⁵ Indeed, there is considerable debate as to whether the European courts have accepted or endorsed an essential facilities doctrine. Therefore, this Article will use the term “essential facilities doctrine” merely as a label, assuming that this term is what most closely captures the principles and propositions laid down in the refusal to supply (or analogous) cases by the relevant courts and the European Commission (the “Commission”).⁶⁶

My focus will be on only one of the limbs of this doctrine, albeit the most fundamental: the requirement of essentiality or indispensability.⁶⁷ More specifically, my effort will be to analyze case law and derive a framework for determining the essentiality or indispensability of a facility. This framework will then be applied to determine the viability of substitutes for patented genes.

a. *Volvo*

A good starting point for analyzing the application of the essential facilities doctrine to intellectual property cases is *AB Volvo v. Erik Veng (UK) Ltd.*⁶⁸ This case concerned the front fenders of certain Volvo cars, on which Volvo held a registered design.⁶⁹ Veng, a British company, imported these products, manufactured reproductions of them, and marketed the reproductions in the United Kingdom without authority from Volvo.⁷⁰ Upon Volvo instituting proceedings for an infringement of its registered design, Veng argued that by refusing access to its design, Volvo had abused its dominant position.⁷¹

The ECJ stressed that a refusal to grant a license to a third party would not “in itself, constitute an abuse of a dominant position.”⁷² Rather, Article 82 requires factors over and above a mere refusal to license.⁷³ The ECJ held that a refusal to license might be abusive if coupled with “an arbitrary refusal to supply spare parts to independent repairers, the fixing of prices for spare parts at an unfair level or a

65. See 1974 E.C.R. 223, Judgment of the Court, para. 25 (holding that a dominant producer of a raw material could not cease supplying an existing customer that manufactured derivatives of the raw material simply because the dominant producer had decided to start manufacturing the derivative itself and wished to eliminate its former customer from the market).

66. See Merges & Nelson, *supra* note 11. See also Lang, *supra* note 57, at 483 (noting that in relation to the term “essential facilities doctrine,” the “concept may be merely a useful label . . . rather than an analytical tool”).

67. For the purpose of this Article, I will assume that the other limbs of this doctrine and Article 82 in general stand satisfied. For example, I assume that the alleged abusive act is committed within the European Community “or a substantial part of it” and that said act “affect[s] trade between Member States.” See *supra* notes 59–60 and accompanying text.

68. Case 238/87, *AB Volvo v. Erik Veng (UK) Ltd.*, 1988 E.C.R. 6211.

69. *Id.* at Opinion of Advocate Gen., para. 2.

70. *Id.*

71. *Id.* paras. 2–3.

72. *Id.* at Judgment of the Court, para. 8.

73. *Id.* para. 9.

decision no longer to produce spare parts for a particular model even though many cars of that model are still in circulation.”⁷⁴

b. *Magill*

A dispute involving several U.K. broadcasters became the first European Community case in which a refusal to license an intellectual property right was held to constitute an abuse under Article 82.⁷⁵ Magill published a weekly television guide containing program schedules for all the television channels in Ireland.⁷⁶ At that time, the broadcasting and television stations (RTE, BBC, and ITP) published separate weekly guides to their own programs.⁷⁷ The broadcasters freely supplied program information to daily newspapers, which were allowed to publish one day's listings (or two days' listings on weekends or where the following day was a public holiday).⁷⁸ Publication of the weekly listings, however, was not authorized; the broadcasters had reserved this right for themselves, relying on Irish copyright rules.⁷⁹ 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.⁸⁰

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 82.⁸¹ The Commission found that the broadcasters had abused their respective dominant positions in the market; their refusal had prevented the introduction into the market of a new product for which there was substantial potential demand.⁸² The Commission therefore ordered that the broadcasters license listings to each other and third parties on a non-discriminatory basis, a decision confirmed by the Court of First Instance (CFI) and the ECJ.⁸³

The ECJ began by cautioning that mere ownership of an intellectual property right would not, by itself, confer dominance.⁸⁴ In this particular

74. *Id.*

75. Commission Decision 89/205, *Magill TV Guide/ITP, BBC and RTE*, 1989 O.J. (L 78) 43. The broadcasters unsuccessfully appealed this decision to the CFI and then the ECJ. Case T-70/89, *British Broad. Corp. v. Comm'n*, 1991 E.C.R. II-535; Case T-69/89, *Radio Telefis Eireann v. Comm'n*, 1991 E.C.R. II-485; Case T-76/89, *Indep. Television Publ'ns Ltd. v. Comm'n*, 1991 E.C.R. II-575, *aff'd sub nom.* Joined Cases C-241/91 P & C-242/91 P, *Radio Telefis Eireann (RTE) v. Comm'n*, 1995 E.C.R. I-743.

76. Commission Decision 89/205, *supra* note 75, at 44.

77. *Id.* at 43-44.

78. *Id.* at 46.

79. *Id.*

80. *Id.*

81. *Id.* at 43.

82. *Id.* at 49.

83. *Id.* at 50-51; *see* cases cited *supra* note 75.

84. Joined Cases C-241/91 P & C-242/91 P, *Radio Telefis Eireann (RTE) v. Comm'n (RTE and ITP)*, 1995 E.C.R. I-743, Judgment of the Court, para. 46.

case, however, the court found that the broadcasters were in a dominant position because they enjoyed a de facto monopoly over the television program information used to compile listings.⁸⁵

In concluding that there was an abuse of a dominant position, the court reiterated the principle in *Volvo* that a mere refusal to license would not constitute an abuse.⁸⁶ Accompanying such a refusal must be exceptional circumstances, which, in this case, the court identified as the refusal's effective suppression of a new product ("a comprehensive weekly guide to television programmes") that the broadcasters "did not offer and for which there was a potential consumer demand."⁸⁷ The court found further that there was "no justification for such refusal either in the activity of television broadcasting or in that of publishing television magazines."⁸⁸ By denying access to "the raw material indispensable for the compilation" of a TV guide, the broadcasters "reserved to themselves the secondary market of weekly television guides by excluding all competition on that market."⁸⁹

Accordingly, the refusal constituted an abuse under Article 82.⁹⁰ However, the court's analysis did not clarify whether the conditions constituting exceptional circumstances were cumulative or distinct. If cumulative, all three conditions must be satisfied prior to determining that a refusal to grant a license amounts to an abuse.⁹¹ This issue was later resolved in favor of the conditions being cumulative by *IMS Health Inc. v. Commission*.⁹²

By evolving an exceptional circumstances framework, *Magill* was perhaps the first case that 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* judgment was a belief that copyright in a mere television listing did not merit intellectual property protection. As one commentator has stated, "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"⁹³

85. *Id.* para. 47.

86. *Id.* para. 49.

87. *Id.* para. 54.

88. *Id.* para. 55.

89. *Id.* para. 56.

90. *Id.* para. 57.

91. *See id.* paras. 48–58.

92. *See* Case T-184/01 R, *IMS Health Inc. v. Comm'n*, 2001 E.C.R. II-3193, paras. 105, 144.

93. Ian S. Forrester, Queen's Counsel, White & Case LLP, Compulsory Licensing in Europe: A Rare Cure to Aberrant National Intellectual Property Rights?, Presentation at the Department of Justice/Federal Trade Commission Hearings 12 (May 22, 2002) (citation omitted), available at <http://www.ftc.gov/opp/intellect/020522forrester.pdf>. This underlying assumption was also hinted at by Advocate General Jacobs in *Bronner* 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

It must be noted that a key factor underlying this judgment was that of essentiality or indispensability. The weekly listings were not reasonably and practically replicable, and no amount of innovation could have produced an alternative.⁹⁴ In the court's words, they were "indispensable raw material."⁹⁵ Surprisingly, the court never expressly articulated essentiality as a separate factor; however, it clearly was an underlying assumption that informed the judgment.⁹⁶ It was not until later cases, namely, the next two discussed below, that the European courts began fleshing out the concept of essentiality or indispensability.

c. *Ladbroke*

The main issue in *Tiercé Ladbroke SA v. Commission* was whether a refusal by Pari Mutuel Urbain Français (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.⁹⁷ The Commission found in favor of PMU.⁹⁸ Upholding the Commission's decision, the CFI rejected an attempt by Ladbroke to invoke *Magill* for two primary reasons: first, PMU was not present in the betting market in Belgium, and, second, the sound and pictures of the races were not essential for Ladbroke's activity.⁹⁹ The CFI went on to apply the essentiality limb:

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.¹⁰⁰

d. *Bronner*

Although intellectual property was not at issue in *Oscar Bronner GmbH v. Mediaprint Zeitungs- und Zeitschriftenverlag GmbH*,¹⁰¹ the case

effort." Case C-7/97, *Oscar Bronner GmbH v. Mediaprint Zeitungs- und Zeitschriftenverlag GmbH*, 1998 E.C.R. I-7791, Opinion of Advocate Gen., para. 63.

94. See generally *RTE and ITP*, 1995 E.C.R. I-743.

95. *Id.* at Judgment of the Court, para. 53.

96. See generally *id.*

97. See Case T-504/93, *Tiercé Ladbroke SA v. Comm'n*, 1997 E.C.R. II-923, paras. 13–14, 109–111, 123–134.

98. *Id.* para. 22.

99. *Id.* paras. 130–132.

100. *Id.* para. 132.

is extremely significant as perhaps the first to engage 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.¹⁰² The key issue was whether Mediaprint's nationwide home-delivery network for newspapers constituted an essential facility.¹⁰³

The ECJ reiterated that a refusal to license is abusive only in exceptional circumstances, that is, if (1) the refusal to give Bronner access to Mediaprint's home delivery system would be likely to eliminate all competition in the daily newspaper market; (2) such refusal could not be objectively justified; and (3) 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.¹⁰⁴ 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.¹⁰⁵ The court elaborated:

Moreover, it does not appear that there are any technical, legal or even 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 use it to distribute its own daily newspapers.¹⁰⁶

The court also found that other methods of distribution such as by mail and by sale in shops or kiosks were available, even if they constituted less advantageous means of distribution.¹⁰⁷ In this sense, the court was stressing the fact that a mere disadvantage would not constitute an "economic obstacle."¹⁰⁸ Further, to accept the existence of economic obstacles, it must be established that the creation of products or services by a competitor was not economically viable for production on a scale comparable to that of the undertaking that controlled the essential facility in question.¹⁰⁹

The ECJ also pointed out that the test of economic feasibility was an objective one. As such, Bronner was required to show not only that it could not develop an alternative home-delivery system, but that an alternative home-delivery system was not economically viable for any of

101. See Case C-7/97, *Oscar Bronner GmbH v. Mediaprint Zeitungs- und Zeitschriftenverlag GmbH*, 1998 E.C.R. I-7791, Opinion of Advocate Gen., para. 4 (concerning Mediaprint's home-delivery network).

102. *Id.*

103. *Id.* paras. 33–34, 49–53.

104. *Id.* at Judgment of the Court, para. 41. This case came 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). *Id.* at Opinion of Advocate Gen., para. 1.

105. *Id.* at Judgment of the Court, para. 42.

106. *Id.* para. 44.

107. *Id.* para. 43.

108. *Id.*

109. *Id.* para. 46.

Mediaprint's actual or potential competitors in the daily newspaper market.¹¹⁰ Finally, as Advocate General Jacobs had pointed out in his opinion, 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.¹¹¹

Bronner represents the first case where the court focused 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 crystallized in terms of the following propositions. First, 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. Second, while assessing the economic viability 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 newspapers. Third, mere economic disadvantage is not the same as economic non-viability and will not count while categorizing a facility as essential. Finally, the test for assessing viability must be objective, focusing on the viability of competition for any other party, not merely the viability of competition for the entity requesting access to the essential facility.

e. *IMS Health*

IMS Health GmbH v. NDC Health GmbH involved a series of proceedings, some before the European Commission and courts and some before national courts. The key issues were referred to the ECJ, which handed down its judgment in 2004.¹¹²

IMS Health ("IMS") is a world leader in data collection pertaining to pharmaceutical sales and prescriptions. In pursuance of its business, it created an "1860 brick structure," which segments Germany into sales zones or bricks.¹¹³ The purpose of 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

110. *See id.* The Advocate General, 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. *Id.* at Opinion of Advocate Gen., para. 58.

111. "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).'" *Id.* at Opinion of Advocate Gen., para. 67.

112. *See generally* Case C-418/01, *IMS Health GmbH v. NDC Health GmbH*, 2004 E.C.R. I-5039.

113. *Id.* at Judgment of the Court, para. 4.

pharmacy, as this would contravene German data protection rules.¹¹⁴ The 1860 brick structure soon developed into a de facto industry standard and came to be widely used by German pharmaceutical companies to analyze sales trends, measure market shares, and gauge the performance of sales representatives.¹¹⁵ IMS claimed copyright over its brick structure and successfully brought actions before German courts against competitors using the structure.¹¹⁶

During the course of these national proceedings, one competitor, NDC Health (“NDC”), complained to the Commission and alleged that IMS’s refusal to license the brick structure amounted to an abuse under Article 82.¹¹⁷ The Commission found in favor of NDC and passed an interim order requiring IMS to grant licenses to competitors.¹¹⁸

i. Commission Decision

In large part, the Commission’s decision turned on the fact that certain obstacles made it almost impossible for competitors to create a new structure for regional sales data in Germany. These obstacles could be categorized in the *Bronner* mold as legal, technical, and economic obstacles.

Of the various obstacles that made it impossible or extremely difficult to create an alternative brick structure, the economic obstacles were perhaps the most significant. 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.”¹¹⁹ The substantial role that pharmaceutical companies played in the design of the 1860 brick structure contributed to this dependency.¹²⁰

Consequently, availing of another structure would have entailed significant switching costs by pharmaceutical companies. More specifically, a new structure would have entailed changing the territories

114. In Germany, the data privacy protection rules, *Bundesdatenschutzgesetz* (Federal Data Protection Act), as most recently amended on May 23, 2001, require that at least three pharmacies be aggregated. Commission Decision 2001/165, NDC Health/IMS Health, 2001 O.J. (L 59) 18, 20, 49 n.7.

115. *See id.* at 22.

116. Commission Decision 2003/741, NDC Health/IMS Health, 2003 O.J. (L 268) 69, 69 (“In particular, the . . . Frankfurt District Court . . . had granted between October and December 2000, separate injunctions prohibiting . . . competitors of IMS on the regional pharmaceutical sales data services market, from using structures derived from the 1 860 [sic] brick structure on the basis that IMS enjoyed copyright protection.”). These injunctions were later slightly modified by an appellate court to permit some alternative structures. *See generally id.* This ruling, coupled with the fact that NDC’s position improved (such that there was no longer any urgency), subsequently led the Commission to withdraw the interim measures on August 13, 2003. *Id.* at 71.

117. *See* Commission Decision 2001/165, *supra* note 114, at 19.

118. *Id.* at 46–47.

119. *Id.* at 29.

120. “The input which the pharmaceutical companies have made to the structure has 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.” *Id.* at 43.

in which sales representatives operated,¹²¹ leading to disruptions in existing relationships between sales representatives and the doctors that they routinely visited, as well as modification of employment agreements between the pharmaceutical companies and their sales representatives.¹²² Moreover, an alternative brick structure also would have necessitated the costly modification of existing software used by pharmaceutical companies.¹²³ As the Commission succinctly summarized, “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 a [sic] unviable economic proposition.”¹²⁴

The legal obstacles presented themselves in the form of copyright law, which prevented the creation of structures similar to the 1860 brick structure,¹²⁵ and data protection law, which limited the number of ways in which copyright in the 1860 brick structure could be circumvented by the creation of alternatives.¹²⁶

The Commission highlighted reliance on postal codes as a prominent technical obstacle that rendered the creation of an alternative impossible or extremely difficult.¹²⁷ 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 [sic] integrated is [sic] provided in this format [and] it appears the only practical way to allocate doctors and pharmacies to particular bricks”¹²⁸ The Commission therefore concluded that “the clear importance of using postcode areas limits the choices available to potential designers of new brick structures.”¹²⁹

Based on all the above, the Commission found as follows:

In this case, in the specific and exceptional circumstances in which the . . . 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.¹³⁰

121. *Id.* at 29.

122. *Id.* at 33.

123. *Id.* at 34.

124. *Id.* at 29.

125. *See id.* at 37. 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. *Id.*

126. “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.” *Id.*

127. *See id.* at 36.

128. *Id.*

129. *Id.* at 35.

130. *Id.* at 43.

ii. CFI Decision

The President of the CFI suspended the Commission decision on the ground that the Commission seemed to take a fairly liberal view of the notion of exceptional circumstances articulated in *Magill*.¹³¹ In particular, the CFI expressed concern that the Commission regarded the *Magill* conditions as non-cumulative; that is, 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.¹³² This order of the CFI, however, did not overrule the Commission's assessment of essentiality or indispensability of the 1860 brick structure.¹³³

iii. ECJ Decision

As mentioned earlier, IMS had complained to the Commission during the course of national proceedings.¹³⁴ The Commission's ruling was appealed to the CFI and thereafter to the ECJ.¹³⁵ During the course of the national proceedings, the national courts referred certain questions separately to the ECJ. First, the national courts asked whether the mere refusal by IMS to license a brick structure that was akin to an industry standard would contravene Article 82.¹³⁶ The ECJ answered that mere indispensability (as a standard), by itself, would not constitute "abuse."¹³⁷ Rather the exceptional circumstances drawn out by *Magill* must be present.¹³⁸ In the court's words:

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

131. The President of the 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 Article 230 of the E.C. Treaty. Case T-184/01 R, *IMS Health Inc. v. Comm'n*, 2001 E.C.R. II-2349, para. 28; Case T-184/01 R, *IMS Health Inc. v. Comm'n*, 2001 E.C.R. II-3193, para. 150.

132. In this regard, the Commission had held, "As clarified in the *Ladbroke* judgment, there is no requirement for a refusal to supply to prevent the emergence of a new product in order to be abusive." Commission Decision 2001/165, *supra* note 114, at 42.

133. *See id.* at 19.

134. Case C-418/01, *IMS Health GmbH & Co. OHG v. NDC Health GmbH & Co. KG*, 2004 E.C.R. I-5039, Judgment of the Court, para. 2.

135. *Id.* paras. 13-15.

136. Although the word "standard" was not explicitly used in this question, the notion of a standard was implied. *See id.* paras. 18, 21.

137. *Id.* para. 34.

138. *Id.* paras. 35-36.

offered by the owner of the right and for which there is a potential consumer demand.¹³⁹

It is important to note that the court also clarified that the *Magill* conditions constituting the exceptional circumstances framework were cumulative.¹⁴⁰ Thus, the court endorsed the CFI objection to the Commission, reading the *Magill* conditions as separate and distinct.¹⁴¹ Also, with regard to the traditional two-market distinction and the need to identify two distinct markets, the ECJ endorsed the view in *Bronner* that “it is sufficient that a potential market or even hypothetical market can be identified.”¹⁴²

The national courts also inquired as to what significance, if any, the pharmaceutical industry’s involvement in developing the 1860 brick structure and its potential switching costs in moving to an alternative structure should have in the courts’ assessment of whether a refusal to license the 1860 brick structure constituted an abuse.¹⁴³ The ECJ clarified that these factors would be relevant to an assessment of whether the facility is essential or indispensable in the first place.¹⁴⁴

In the process of answering these questions, the ECJ did engage in some discussion of the essentiality or indispensability of the brick structure.¹⁴⁵ The court endorsed the key test in *Bronner* requiring, at the very least, that the creation of an alternative was impossible or extremely difficult owing to legal, technical, or economic obstacles.¹⁴⁶ However, unlike the Commission, the ECJ did not delve into this issue in detail; rather, it categorized the issue of whether the structure constituted an essential facility as a factual one ultimately to be determined by the national courts.¹⁴⁷ This conclusion stems from the fact that the above issues came before the ECJ by way of referral from a national court.¹⁴⁸ The Commission, on the other hand, faced no such constraints and, therefore, engaged the question in a more substantial way.¹⁴⁹

139. *Id.* para. 49.

140. *Id.* paras. 37–38.

141. *Id.* paras. 38–39.

142. *Id.* para. 44. 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 European Community or a substantial part of it stand satisfied. See *supra* note 67 and accompanying text.

143. *IMS Health*, 2004 E.C.R. I-5039, Judgment of the Court, para. 23.

144. *Id.* paras. 25–47.

145. *Id.*

146. *Id.* para. 28.

147. *Id.* para. 29.

148. See *id.* para. 18.

149. 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.

C. *Assessing Essentiality: Legal, Technical, and Economic Viability*

Although the European courts have yet to work out fully the parameters of the essential facilities doctrine, some broad conclusions can be drawn from case law. First, the essential facilities doctrine is a subset of the wider mandate to refrain from abusing a dominant position under Article 82. Dominance in a given market must be established prior to a finding that there has been an abuse.¹⁵⁰ The courts have been cautious to state that mere ownership of intellectual property would not, by itself, confer dominance.¹⁵¹

Second, a mere refusal to license an intellectual property is not sufficient to invoke the essential facilities doctrine.¹⁵² Rather, as stressed in *Volvo*, there must be additional exceptional circumstances.¹⁵³ 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 Health*.¹⁵⁴ Considerations include whether (1) 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; (2) the facility is indispensable to carrying on business, inasmuch as there is no actual or potential substitute for that facility; (3) the refusal is not capable of being objectively justified; and (4) the refusal is likely to foreclose all competition in the secondary market. An English case, however, has held that the exceptional circumstances factors drawn out by the ECJ and CFI are not exhaustive but could admit of other situations as well in the future.¹⁵⁵ The U.K. Court of Appeal observed that this approach was warranted by the “width of the descriptions of abuse contained in Art. 82 itself.”¹⁵⁶

Of all the exceptional circumstances factors, the one that truly underpins the essential facilities doctrine is essentiality or indispensability. Clearly, if the facility is non-essential, other limbs of this doctrine need not be examined. Essentiality formed a significant portion of the underlying judicial reasoning in *Magill*, *Bronner*, and *IMS Health*.¹⁵⁷ In *Magill*, the weekly listings were not reasonably and practically replicable; they were very essential and no amount of

150. See Joined Cases C-241/91 P & 242/91 P, *Radio Telefis Eireann (RTE) v. Comm'n*, 1995 E.C.R. I-743, Opinion of Advocate Gen., para. 53.

151. *Id.* at Judgment of the Court, para. 46.

152. See *id.* paras. 46, 49.

153. Case 238/87, *AB Volvo v. Erik Veng (UK) Ltd.*, 1988 E.C.R. 6211, Judgment of the Court, para. 9.

154. *IMS Health* clearly reiterates that the exceptional circumstances test is here to stay. See Bruno LeBrun, Case Comment, *IMS v NDC: Advocate General Tizzano's Opinion*, 26 EUR. INTELL. PROP. REV. 84, 87 (2004).

155. *Intel Corp. v. VIA Techs. Inc.*, [2002] EWCA (Civ) 1905, [48] (Eng.). For an analysis of this decision, see Duncan Curley, *Eurodefences and Chips: "A Somewhat Indigestible Dish,"* 25 EUR. INTELL. PROP. REV. 282 (2003).

156. *Intel*, [2002] EWCA (Civ) 1905, [48].

innovation could have produced an alternative.¹⁵⁸ In *Bronner*, the ECJ stipulated a high threshold for essentiality, holding that mere inconvenience in duplicating the essential facility in question would not suffice.¹⁵⁹ In *IMS Health*, 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.¹⁶⁰ Although *Magill* and *IMS Health* were copyright cases and *Bronner* did not involve intellectual property, to the extent that these cases lay down a broad framework for determining indispensability or essentiality, their principles could be transposed to patent cases as well.¹⁶¹

Bronner was the first case to elucidate a broad framework for assessing the essentiality or indispensability of a facility.¹⁶² The propositions of the *Bronner* framework are set forth above.¹⁶³ Amongst these propositions, the critical and perhaps most difficult one to assess is the existence of legal, technical, and economic obstacles that would render the creation of an alternative facility impossible or extremely difficult.¹⁶⁴ Quite clearly, all three parameters (legal, technical, and economic) must be assessed to make a final determination of the essentiality or indispensability of a facility.¹⁶⁵

For the sake of generating an easy-to-use and a somewhat mathematical framework, I have attempted to retain the essence of the *Bronner* framework but adapt it in two significant ways. First, the proposition that the creation of the facility must be impossible or extremely difficult owing to legal, technical, and economic obstacles should be replaced with the following: 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 embracing the notions of "impossibility" or "extreme difficulty" in creating alternatives. Second, because neither *Bronner* nor any of the

157. Commission Decision 89/205, *supra* note 75, at 50; Case C-7/97, Oscar Bronner GmbH v. Mediaprint Zeitungs- und Zeitschriftenverlag GmbH, 1998 E.C.R. I-7791, Judgment of the Court, paras. 37–38; Commission Decision 2003/741, *supra* note 116, at 70. 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. *See generally* *Bronner*, 1998 E.C.R. I-7791; Commission Decision 89/205, *supra* note 75. 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. *See* Commission Decision 89/205, *supra* note 75, at 50.

158. In fact, in *Magill*, even attempting an alternative would have been illogical, as a compilation of television listings would always require that the listings be reproduced. *See* Commission Decision 89/205, *supra* note 75, at 50.

159. *See supra* notes 105–09 and accompanying text.

160. Commission Decision 2003/741, *supra* note 116, at 69.

161. *See, e.g.,* *Bronner*, 1998 E.C.R. I-7791, Judgment of the Court, paras. 38–47.

162. *See supra* Part III.B.2.d.

163. *Id.*

164. *See id.*

165. *See id.*

other cases have laid down a specific order for assessing the viability of an alternative or substitute, this Article proposes the following order: (1) determine the legal viability of an alternative facility; (2) if the alternative is legally viable, evaluate its technical viability; and (3) if the alternative is technically viable, assess its economic viability.

1. *Legal Viability*

The above order has some advantages. For a competition authority or a judge, assessing what constitutes a legal obstacle would be a relatively easier and more objective task 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 because such facility would have had to replicate the television listings.¹⁶⁶ The legal obstacle, therefore, was one that was impossible to transcend.

Yet it is important to note that *Magill* was an exception and 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 some amount of inventing around or designing around.

Estimating the exact latitude that exists for such designing around is a complex task, as shown by *IMS Health*.¹⁶⁷ 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.¹⁶⁸ The Commission concluded from this that there were no legally viable alternatives to the 1860 brick structure.¹⁶⁹

At a later point in time, however, an appellate court in Germany qualified the findings of the lower court in relation to the scope of copyright over the 1860 brick structure and seemed to suggest that some of the competing structures did not infringe.¹⁷⁰ In pertinent part, the German appellate court held, "The 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."¹⁷¹ Along with other factors, this finding by the

166. See Commission Decision 89/205, *supra* note 75, at 48–49.

167. Commission Decision 2001/165, *supra* note 114; Commission Decision 2003/741, *supra* note 116.

168. Commission Decision 2001/165, *supra* note 114, at 18, 22–23.

169. *Id.* at 37.

170. Commission Decision 2003/741, *supra* note 116, at 71.

171. *Id.* (providing a translation of the judgment).

appellate court convinced the Commission to withdraw its interim order.¹⁷²

One way of resolving such complexities could be to relegate all borderline cases to the category of “legally non-viable” because any substitute would be legally uncertain. In fact, in *IMS Health*, the Commission adopted such an approach:

[T]he Frankfurt Court judgment 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 [the 1860 brick structure]. The Court did not define precisely what it would consider to be derivatives, and no clarification is likely for around three years. Pharmaceutical companies are aware of this uncertainty, having been warned by IMS not to infringe its copyright, and would be sceptical [sic] about the legality of any new structure which competitors of IMS might use to format a new regional sales data service.¹⁷³

Even with this approach, there is still a significant amount of objectivity associated with assessing legal viability. A non-viable alternative could be taken simply to be any alternative that infringes the intellectual property right covering the essential facility in question or one that violates some other law.¹⁷⁴

2. *Economic Viability*

Relative to legal viability, it is more difficult to agree upon the objective parameters for determining economic viability. The Asian Development Bank defines economic viability as “[t]he 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.”¹⁷⁵ This begs the questions, however, of what an additional required rate of return would be and what effective production would entail. Dr. Dimitri Mavris of the Georgia Institute of Technology attempts another definition of economic viability: “a measure of the system’s ability to achieve specified cost and profitability goals as well as satisfy any constraints imposed.”¹⁷⁶ Here again, one is forced to query about the specified cost and profitability goals. Thus, economic viability may not be as objectively determinable

172. *Id.*

173. Commission Decision 2001/165, *supra* note 114, at 37.

174. Legal non-viability also could stem from the potential to transgress some other law. In *IMS Health*, limitations stemming from data protection law constituted a legal obstacle hampering the creation of viable alternative facilities. *Id.*

175. Asian Development Bank, *Economic Analysis of Projects: Glossary of Terms*, http://www.adb.org/Documents/Guidelines/Eco_Analysis/glossary.asp (last visited Nov. 25, 2005).

176. Dimitri N. Mavris et al., Ga. Inst. of Tech., *Demonstration of a Probabilistic Technique for the Determination of Aircraft Economic Viability*, Presentation at the Second World Aviation Congress and Exposition 5 (Oct. 13–16, 1997), available at <http://www.asdl.gatech.edu/publications/pdf/1997/AIAA-97-5585.pdf>.

as legal viability or even technical viability.¹⁷⁷ Therefore, this part of the evaluation is best relegated to the end.

3. *Technical Viability*

The difficulty of evaluating technical viability lies somewhere between that of legal viability and economic viability. 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 the source of the water.¹⁷⁸

For patented genes, the technical viability of a substitute could be analyzed in accordance with the above physical parameters by asking, “Will the substitute be as effective in its function as the patented gene?” In the particular context of genetics, which is a rapidly evolving and uncertain science, asking whether an alternative is technically feasible (that is, whether it can guarantee the same result) is not an easy task. However, when compared with economic feasibility, it is far more objective, as the basic inquiry can be reduced to determining whether an alternative is technically possible given the current state of technology.

Of course, by their very nature questions of technical feasibility would invite issues of economic feasibility, with which they are inexorably linked. However, for the purposes of analysis here, it helps to keep them separate.

Because 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, because economic viability would involve considering factors that are less definite than those pertaining to legal or technical viability, this assessment could perhaps be undertaken last.

177. 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. See Case C-7/97, *Oscar Bronner GmbH v. Mediaprint Zeitungs- und Zeitschriftenverlag GmbH*, 1998 E.C.R. I-7791, Judgment of the Court, paras. 41–47.

178. Aaron T. Wolf & Masahiro Murakami, *Techno-Political Decision Making for Water Resources Development: The Jordan River Watershed*, 11 WATER RES. DEV. 147, 151 (1995).

IV. HOW "ESSENTIAL" IS A PATENTED GENE?

*If necessity has been regarded through the ages as the mother of "invention," then patent law ought to be considered the mother of "inventing around."*¹⁷⁹

As has been stressed above, in the context of patented technologies, the question of essentiality or indispensability hinges in large part on the availability and viability of substitutes or alternatives that are, in most cases, created by inventing around the technology in question.

A. *Alternatives or 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.¹⁸⁰ Thus, for example, Dr. Gert 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 gene and each gene sequence is unique in its kind. Hence, through patenting, a "double" monopoly arises.¹⁸¹

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."¹⁸²

My attempt is to cast some doubt on this proposition, at least insofar as it is stated in absolute terms. Certainly, inventing around a patented gene may be much more difficult when compared to other patented inventions. As illustrated by the examples below, however, it is not an impossible task.

179. This quote is the author's own, though it extends Plato's remarks. See PLATO, THE REPUBLIC 40 (Joslyn T. Pine ed., Benjamin Jowett trans., Dover Publications 2000) (n.d.) ("[T]he true creator is necessity, who is the mother of our invention.").

180. See Matthijs & Halley, *supra* note 24, at 784; Andrews, *supra* note 20, at 78–79.

181. Gert Matthijs, *Patenting Genes*, 329 BRIT. MED. J. 1358, 1359 (2004); see also Matthijs & Halley, *supra* note 24, at 784.

182. Andrews, *supra* note 20, at 78–79.

1. *Gene Variants or Animal Genes*

A patent on a gene could be circumvented by deploying a variant of the gene.¹⁸³ In fact, because some animal genes are similar in structure and function to human genes, it even may be theoretically possible to substitute an animal gene for a human gene. 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 BRCA1.¹⁸⁴ Experts opined that this gene could offer some clues regarding the development of breast and ovarian cancer.¹⁸⁵ Given Myriad's high licensing fees and its threat to enforce patents strictly, even against universities,¹⁸⁶ 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.¹⁸⁷

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, therefore, may 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, however, will be undertaken in more detail later.

2. *Gene Switching or Gene Activation*

To appreciate the ingenuity underlying gene switching and gene activation, one must journey back in time to recollect that the initial grants of gene patents (and, indeed, even the current ones) were based substantially on a legal sophistry.¹⁸⁸ Although the gene itself existing in its natural state could not be patented, isolating or purifying it in some

183. 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, regardless of whether it belongs to the same family as the original gene (homologous).

184. *Primitive Worm Gives Cancer Clue*, BBC NEWS, Jan. 6, 2004, <http://news.bbc.co.uk/1/hi/health/3368685.stm>.

185. *Id.*

186. Steve Bunk, *Researchers Feel Threatened by Disease Gene Patents*, SCIENTIST, Oct. 11, 1999, at 7.

187. *Legalities: Having a Patent May Not Protect You*, RED HERRING, Sept. 1, 2000, <http://www.redherring.com/PrintArticle.aspx?a=4341§or=Archive> ("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.").

188. For a good critique of this sophistry, see John M. Conley & Roberte Makowski, *Back to the Future: Rethinking the Product of Nature Doctrine as a Barrier to Biotechnology Patents* (pts. 1 & 2), 85 J. PAT. & TRADEMARK OFF. SOC'Y 301, 371 (2003).

form magically swept it past the “product of nature” hurdle.¹⁸⁹ Patents thus were 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 now could be flipped on its head. If the gene in its natural state (or genetic information) 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].”¹⁹⁰

Companies are coming to strategically use this technique, popularly referred to as “gene switching” or “gene activation,”¹⁹¹ to design around existing gene patents.¹⁹² 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.”¹⁹³ 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 such that they could be administered directly to a patient.¹⁹⁴ The zinc finger turns on a gene that expresses the medically important protein inside the body, circumventing the need for purifying the protein or removing it from the cell.¹⁹⁵

An example of gene activation that is more familiar to patent lawyers and scholars is the creative deployment of a “switching” technique. Used by Transkaryotic Therapies to circumvent Amgen’s patents on erythropoietin (EPO) and its corresponding gene, this technique spawned a series of law suits on both sides of the Atlantic.¹⁹⁶

189. Rebecca S. Eisenberg, *Re-Examining the Role of Patents in Appropriating the Value of DNA Sequences*, 49 EMORY L.J. 783, 786 (2000); see also *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948) (“[P]atents cannot issue for the discovery of the phenomena of nature.”).

190. Gary Stix, *Legal Circumvention: Molecular Switches Provide a Route Around Existing Gene Patents*, SCI. AM., July 2002, at 36, 36.

191. The scientific term for this technique is “endogenous gene activation.” See *id.*

192. *Id.*

193. *Id.*

194. *Id.*

195. *Id.*

196. This legal saga began with the filing of a declaratory judgment action by Kirin-Amgen Inc. (“Amgen”) against Hoechst Marion Roussel, Inc., and Transkaryotic Therapies (collectively “TKT”) in the United States alleging that TKT’s EPO product infringed Amgen’s patents. *Amgen, Inc. v. Hoechst Marion Roussel, Inc. (Amgen III)*, 339 F. Supp. 2d 202, 213 (D. Mass. 2004). There were proceedings in other jurisdictions as well, including the United Kingdom, Australia, and the Netherlands. See *The House of Lords Wakes Up: Kirin Amgen v Hoechst*, EUR. IP BULL.

EPO is a very important hormone made in the kidneys that stimulates the production of erythrocytes (red blood cells) in the bone marrow. It therefore has tremendous utility in the treatment of anemia, particularly when such anemia 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 anemic patients.¹⁹⁷

This is where Amgen's deployment of recombinant DNA (r-DNA) technology for the production of large quantities of human EPO proves immensely useful.¹⁹⁸ 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.¹⁹⁹ In this case, the human EPO DNA is exogenous to the hamster host cell. Amgen holds patents not only on this process for producing EPO, but also on the EPO gene and the EPO end-product.²⁰⁰

By contrast, TKT does not use a host cell from a non-human species to produce its human EPO.²⁰¹ 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.²⁰² 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 United Kingdom, it failed to convince courts in the United States, where

(McDermott Will & Emery, London, U.K.), Nov. 2004, at 1, 1, available at <http://www.mwe.com/info/news/euroip1104.pdf>.

197. Amgen, Inc., Recombinant DNA Technology, http://www.amgen.com/science/about_biotechnology_recombinant_dna_technology.html (last visited Nov. 28, 2005).

198. This r-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 . . .

Basheer, *supra* note 18, at 4–5 (citations omitted).

199. See Debra Robertson, *First Round to Amgen in EPO Battle*, 18 NATURE BIOTECH. 483, 483 (2000), available at http://www.nature.com/nbt/journal/v18/n5/pdf/nbt0500_483.pdf.

200. Karen Pihl-Carey, *Amgen Suing Roche for Infringing on EPO Patents*, BIOWORLD TODAY, Nov. 10, 2005, http://bioworld.com/servlet/com.accumedia.web.Dispatcher?next=bioworldHeadlines_article&forceid=36909. Amgen's EPO product (marketed under the name EPOGEN) was launched in 1989. See EPOGEN, History of EPOGEN, http://www.epogen.com/professional/about/epogen_history.jsp (last visited Nov. 25, 2005). Since that time, the product has become a huge success, earning billions of dollars in sales. Alex K. Pavlou & Janice M. Reichert, *Recombinant Protein Therapeutics—Success Rates, Market Trends and Values to 2010*, 22 NATURE BIOTECH. 1513, 1516 (2004), available at <http://www.nature.com/nbt/journal/v22/n12/pdf/nbt1204-1513.pdf>.

201. Robertson, *supra* note 199, at 483.

202. See *Kirin-Amgen Inc. v. Hoechst Marion Roussel Ltd.*, [2004] UKHL 46, [2005] 1 All E.R. 667, [10] (Eng.). TKT sought to market its product under the name Dynepo, but the product is also referred to as Gene-Activated EPO (“GA-EPO”). *Id.* at [2]. Although the EPO gene is present in all human cells, in most cells it is dormant or turned off. Robertson, *supra* note 199, at 483.

TKT was held to infringe.²⁰³ This legal saga will be elaborated upon later to demonstrate that even such ingenious switching techniques may not be free of legal risk.

3. Offshore Research

Another strategy increasingly used in the biopharmaceutical industry today is to conduct research involving patented products or 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 ruling by the Federal Circuit in *Bayer AG v. Housey Pharmaceuticals, Inc.*,²⁰⁴ which stated that if the result of using a patented process is “information” and not a product, then importing such information into the United States would not amount to a patent infringement.

Housey owned a number of U.S. patents relating to methods of screening for, or identifying compounds with, stimulatory or inhibitory activity against certain proteins.²⁰⁵ These compounds consequently had the potential for development as pharmaceuticals.²⁰⁶ Bayer employed the screening method in Europe to identify compounds that it then developed as the active ingredient of certain pharmaceutical compositions.²⁰⁷ As Housey alleged, Bayer proceeded to import and sell these pharmaceutical compositions in the United States.²⁰⁸

Housey brought proceedings against Bayer for patent infringement under 35 U.S.C. § 271(g).²⁰⁹ That section provides in relevant part:

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.²¹⁰

Upholding the dismissal of Housey’s complaint by the district court, the Federal Circuit rejected Housey’s argument that information obtained using Housey’s patented process was a product within the meaning of the statute.²¹¹ The court clarified that infringement under § 271(g) is limited to physically manufactured goods and declined to extend the protection of the statute to information generated by a patented process.²¹²

203. See *infra* Part IV.B.1.a.ii.

204. *Bayer AG v. Housey Pharm., Inc.*, 340 F.3d 1367, 1377–78 (Fed. Cir. 2003).

205. *Id.* at 1369.

206. See *id.* at 1369–70.

207. See *id.*

208. *Id.* at 1370.

209. *Id.* at 1369.

210. 35 U.S.C. § 271(g) (2000).

211. *Bayer*, 340 F.3d at 1376–77.

212. *Id.* at 1377.

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.²¹³ The court held that § 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."²¹⁴ Accordingly, the court concluded, "A drug product, the characteristics of which were studied using the claimed research processes [was] not a product 'made by' those claimed processes."²¹⁵

Under *Bayer*, therefore, a patentee cannot exclude importation of either information or products not directly obtained from the patented process.²¹⁶ Although the imported information in the case of *Bayer* 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 following examples. Synergene, a Maltese company, conducts diagnostic tests using Myriad's patented BRCA genes and ships the results (information) back to customers in countries where the patent exists.²¹⁷ Needless to say, this is possible owing to the fact that Myriad's inventions are not patented in Malta.²¹⁸ Similarly, NimbleGen, a U.S. company, is reported to be strategically using the patented processes of Affymetrix to produce custom microarrays in Iceland.²¹⁹ Because Affymetrix 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 protected by patent.²²⁰ Not too surprisingly, Affymetrix closely followed the *Bayer* case and even filed an amicus brief, arguing that patent law does not differentiate between information and physical products.²²¹ It is important to remember 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. Laws could also be amended to bring such strategic "offshoring" within the ambit of patent infringement.

213. *Id.* at 1377-78.

214. *Id.* at 1378.

215. *Id.*

216. *Id.*

217. Erika Check, *Malta Provides Loophole for Breast-Cancer Screen*, 419 NATURE 767, 767 (2002). Unfortunately, this testing was discontinued recently by Synergene. E-mail from Kevin Camilleri, Operations Dir., Synergene Biotech. Group, to author (Nov. 5, 2004) (on file with author).

218. Check, *supra* note 217, at 767.

219. See Meredith Salisbury, *Is Data a Product? Patent Kings Fear IP Goes Outside the Law*, GENOME TECH., Feb. 4, 2004, <http://www.genomeweb.com/articles/viewarticle.asp?Article=20042316229>.

220. *Id.*

221. *Id.*; see also Brief of Amici Curiae Affymetrix, Inc., et al. in Support of Neither Party and in Support of Reversal or Vacatur, *Bayer*, 340 F.3d 1367 (2003) (No. 02-1598), 2002 WL 32817221.

Similar to § 271(g), section 60(1)(c) of the U.K. Patents Act declares it an infringement of a patented process to sell, use, or import into the United Kingdom a product that is the direct result of a patented process.²²² The section provides, “[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.”²²³ Although the United Kingdom has not seen a *Bayer*-like case—where a 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*.²²⁴ Pioneer held a patent in the United Kingdom for processes relating to the manufacture of master disks, which were used for the mass production of compact disks (CDs).²²⁵ The patent, however, allegedly covered only the process of producing master disks and not the process of producing CDs from the master disks.²²⁶ Pioneer sued Warner for importing CDs into the United Kingdom that had been made outside the United Kingdom from the master disks.²²⁷ Warner argued that the CDs were not products obtained directly from the patented process.²²⁸

The Court of Appeal upheld the lower court decision that the finished CDs were the result of three further stages of production and therefore were materially different from the master disks.²²⁹ The court further noted that neither the master disk nor any of the intermediate products were capable of performing the same function as the finished disk.²³⁰

It would be fair to state that this decision is broadly reflective of the European position as well.²³¹ In fact, in reaching its decision, the *Pioneer* court held that by virtue of § 130(7) of the Patents Act, section 60(1)(c) must be construed in line with the European Patent Convention

222. Patents Act, 1977, c. 37, § 60(1)(c) (U.K.).

223. *Id.*

224. *Pioneer Elecs. Capital Inc. v. Warner Music Mfg. Eur. GmbH (Pioneer II)*, [1997] R.P.C. 757.

225. *Pioneer Elecs. Capital Inc. v. Warner Music Mfg. Eur. GmbH (Pioneer I)*, [1995] R.P.C. 487, 489.

226. *Id.* at 490–91.

227. *Id.* at 489.

228. *Id.* at 490.

229. *Pioneer II*, [1997] R.P.C. at 758, 774.

230. *Id.* at 764–65.

231. As used here, the term “European position” refers generally to the principles laid down in European patent instruments such as the European Patent Convention (EPC) and the Community Patent Convention (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 because these courts are looking more to the European Patent Office and decisions of other member states when determining the question of infringement. See GUY TRITON, *INTELLECTUAL PROPERTY IN EUROPE* 55 (1996).

(EPC).²³² Article 64(2) of the EPC states, “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.”²³³

Because Article 64(2) has its origins in German law, the *Pioneer* court turned to the German Patents Act and found that the German equivalent for the term “directly” was *unmittelbar*, a term similar to “without intermediary.”²³⁴ The court therefore held that the section applied to products that were the direct and immediate result of the patented process.²³⁵

It would be interesting to hypothesize how a U.K. court would decide a case like *Bayer*, particularly the information-versus-product dilemma that the U.S. decision sought to address.²³⁶ Because 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 § 60(1)(c). On the issue of whether a drug discovered by using that information would amount to a product under § 60(1)(c), *Pioneer* would resolve this issue in favor of *Bayer*. Much like the U.S. decision, the direct output of the process likely would be seen as information about the chemical compound and not the chemical compound itself.

B. The Viability Issue

I have tried briefly to highlight above some of the ways in which gene patents could be circumvented by the deployment of substitutes or alternatives. However, it remains to be seen whether such substitutes or alternatives would be viable—legally, technically, and economically. I will use the *Bronner* framework to aid me in this investigation.²³⁷ As suggested in Part II, it may be helpful to do the investigation in this order: (1) determine the legal viability of the proposed substitute or alternative; (2) assuming the alternative is legally viable, evaluate the technical viability²³⁸; and (3) if, from a technical standpoint, the alternative is viable, then assess the economic viability of the alternative.²³⁹

232. *Pioneer II*, [1997] R.P.C. at 763.

233. Convention on the Grant of European Patents (European Patent Convention) art. 64(2), Oct. 5, 1973, 13 I.L.M. 287.

234. *Pioneer II*, [1997] R.P.C. at 765–66.

235. *Id.* at 766.

236. *Bayer AG v. Housey Pharm., Inc.*, 340 F.3d 1367, 1368 (Fed. Cir. 2003).

237. *See supra* Part III.B.2.d.

238. Because 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.

239. *See supra* Part III.C.3.

1. *Legal Viability*

Where the essential facility in question is a patented invention, the key question for determining viability is whether the scope of the patent is broad enough to cover the proposed substitute or alternative. This question alone is not determinative; 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. I first discuss patent scope before moving on to the research exemption.

a. Determining Patent Scope

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. Illustratively, while the United States recognizes the doctrine of equivalents, which enables protection of equivalents beyond the literal scope of the claims,²⁴⁰ the United Kingdom does not.

In the United Kingdom, claim scope is determined in accordance with the doctrine of “purposive construction,” well articulated for the first time in the famous *Catnic Components Ltd. v. Hill & Smith Ltd.*²⁴¹ and reflected today in Article 69 of the EPC²⁴² and the corresponding Protocol.²⁴³ In short, this approach entails the following. As opposed to a strict literal interpretation, in construing a patent claim, emphasis must be placed upon what the skilled person would have understood a patentee to mean by the language of the claims.²⁴⁴ The issue of infringement involves a fairly straightforward assessment of whether the infringing product or process falls within the claim scope, thus so purposively construed.²⁴⁵

The hostility of English courts towards the doctrine of equivalents was most recently witnessed in *Kirin-Amgen Inc. v. Hoechst Marion*

240. 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.” *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 21 (1997). *See also* *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 732–33 (2002); *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608 (1950). “The effect of the doctrine is thus to extend protection to something outside the claims which performs substantially the same function in substantially the same way to obtain the same result.” *Kirin-Amgen Inc. v. Hoechst Marion Roussel Ltd.*, [2004] UKHL 46, [2005] 1 All E.R. 667, [38] (Eng.).

241. *Catnic Components Ltd. v. Hill & Smith Ltd.*, [1982] R.P.C. 183, 243.

242. In *Kirin-Amgen*, Lord Hoffman categorically stated that the *Catnic* principle was “precisely in accordance with [Article 69 and the] Protocol.” [2004] UKHL 46, [48]. He also noted that since *Catnic*, the United Kingdom has adopted Article 69, which “firmly shuts the door on any doctrine which extends protection outside the claims.” *Id.* at [44].

243. Protocol on the Interpretation of Article 69 of the Convention, Oct. 5, 1973, 13 I.L.M. 348.

244. *Kirin-Amgen*, [2004] UKHL 46, [34].

245. *See id.*

Roussel Ltd. 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.”²⁴⁶ *Amgen* articulates the United Kingdom’s position on the scope of patent claims in a succinct manner and, therefore, is a good starting point for discussion in this regard. As mentioned above, Amgen, a California pharmaceutical company that held a patent on recombinant EPO for the treatment of anemia, sued TKT for its GA-EPO.²⁴⁷ While in the United Kingdom the legal outcome favored TKT, the reverse situation prevailed in the United States.²⁴⁸ I first consider the U.K. ruling.

i. *Amgen*: U.K. position

The House of Lords upheld the unanimous Court of Appeal decision that TKT’s GA-EPO product does not infringe Amgen’s patent.²⁴⁹ However, the House of Lords overruled the Court of Appeal on validity and held that two of the main claims were invalid. While the House of Lords decision covers many interesting issues, including product-by-process claims, insufficiency, anticipation, and purposive construction,²⁵⁰ for purposes of discussion here I will focus only 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.²⁵¹ Lord Hoffman considered in detail the rules of construction appropriate to such a situation before proceeding to apply them to the facts.²⁵² He emphasized,

The 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?²⁵³

Interestingly, Lord Hoffman also warned that the three “Protocol Questions” that he had set out in *Improver Corp. v. Remington*

246. *Id.* at [44]. Lord Hoffman delivered the judgment, with which all the other Law Lords concurred. *See id.* at [134]–[140].

247. *Id.* at [2].

248. *Amgen, Inc. v. Hoechst Marion Roussel, Inc. (Amgen II)*, 314 F.3d 1313, 1358 (Fed. Cir. 2003). Note that the U.S. ruling is not final and could be subject to further appeals.

249. *Kirin-Amgen*, [2004] UKHL 46, [85]. On July 31, 2002, the U.K. Court of Appeal, reversing the earlier decision of the Patents Court, ruled that although the contentious claims (19 and 26) were valid, TKT did not infringe. *See Kirin-Amgen Inc. v. Transkaryotic Therapies Inc.*, [2002] EWCA (Civ) 1096, [155], [2003] R.P.C. 3, 88 (reversing in part the lower court decision in *Kirin-Amgen Inc. v. Transkaryotic Therapies Inc.*, [2002] R.P.C. 2).

250. *Kirin-Amgen*, [2004] UKHL 46, [27]–[35].

251. *Id.* at [2]–[16].

252. *Id.* at [27]–[52].

253. *Id.* at [69].

*Consumer Prods. Ltd.*²⁵⁴ to determine scope were “only guidelines, more useful in some cases than in others.”²⁵⁵

After laying down these rules of construction, Lord Hoffman moved on to apply them to the facts. Of the thirty-one claims in the patent,²⁵⁶ only three (claims 1, 19, and 26) were treated as relevant. Claim 1 concerned “[a] DNA sequence for use in securing the expression of EPO in a host cell,” where the sequence is selected from tables in the patent or from related sequences.²⁵⁷ Claim 19 asserted that EPO is “the product of the expression of an exogenous DNA sequence” and has a higher molecular weight by SDS-PAGE testing than existing EPO derived from extraction from urine.²⁵⁸ Claim 26 stated that EPO is the “product of the expression in a host cell of a DNA sequence according to claim 1.”²⁵⁹ The issue of infringement of the DNA sequence itself (claim 1) did not arise directly, as the alleged infringement was by importation of the EPO product—the subject matter of claims 19 and 26.²⁶⁰ However, the issue of infringement did arise indirectly since claim 26 referred back to claim 1.²⁶¹

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).²⁶² In order to resolve this issue, it is important to appreciate the difference existing between the two underlying technologies.²⁶³ While Amgen’s process for manufacturing EPO relied on an exogenous DNA sequence coding for EPO that was introduced into the host cell, the TKT method involved gene activation of an endogenous DNA sequence by an exogenous upstream control sequence.²⁶⁴ From that distinction in the evidence, the House of Lords concluded that the skilled person would not regard TKT’s method using an endogenous coding sequence to

254. *Improver Corp. v. Remington Consumer Prods. Ltd.*, [1990] F.S.R. 181, 189 (Pat. Ct. 1989). See *Kirin-Amgen*, [2004] UKHL 46, [83]. 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. The following Protocol Questions have become the definitive approach of the English courts to the interpretation issue:

- (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.

Improver, [1990] F.S.R. at 189.

255. *Kirin-Amgen*, [2004] UKHL 46, [52].

256. Eur. Patent No. 0 148 605 B2 (filed Dec. 12, 1984).

257. *Kirin-Amgen Inc.*, [2004] UKHL 46, [12], [13].

258. *Id.* at [12], [14].

259. *Id.* at [12].

260. *See id.*

261. *Id.*

262. *Id.* at [53].

263. *See id.*

264. *See id.* at [58].

produce GA-EPO as one involving a host cell, as required by claim 1.²⁶⁵ Consequently, TKT's GA-EPO was not an EPO as defined in claim 26. Similarly, the House of Lords found convincing the lower court judge's conclusion that the GA-EPO of TKT was not "the product of . . . expression of an exogenous DNA sequence' within claim 19," thus precluding infringement under that claim as well.²⁶⁶

Much in line with its principle of construction outlined earlier, the House of Lords made it abundantly clear that this is where the analysis should end.²⁶⁷ The claim had been construed purposively, and on the facts there was no infringement.²⁶⁸ The court specifically disapproved of any further attempt to apply the Protocol questions over and above that construction.²⁶⁹

ii. *Amgen*: U.S. position

At the outset, it is important to note that the U.S. and U.K. cases cannot be compared directly because the patent claims are not exactly the same. Nonetheless, to the extent that they can be so compared, it would appear that the U.S. courts granted a much broader scope to Amgen's U.S. patent than did the U.K. courts to the corresponding European patent.²⁷⁰

While the U.K. courts relied on the endogenous versus exogenous distinction in concluding that TKT's endogenous process fell outside Amgen's claim scope, the U.S. courts did not want to read in such a limitation into Amgen's claim.²⁷¹ The Federal Circuit articulated its position as follows:

Guided by our principles of claim construction, we agree with the district court that TKT improperly seeks to import the "exogenous"

265. *Id.* at [58], [80].

266. *See id.* at [58].

267. *See id.* at [69].

268. *See id.* at [58].

269. *Id.* at [70] ("[O]nce the judge had construed the claims as he did, he had answered the question of infringement. It could only cause confusion to try to answer the Protocol questions as well.").

270. *See* James Nurton, *Lords Reject Equivalents Test*, *MANAGING INTELL. PROP.*, Oct. 24, 2004, <http://www.managingip.com> (search for "Lords Reject Equivalents Test"; then follow hyperlink to story) ("The patent claims at issue in the US are not directly comparable to those in the European patent.").

271. *Amgen, Inc. v. Hoechst Marion Roussel, Inc. (Amgen I)*, 126 F. Supp. 2d 69, 89 (D. Mass. 2001). The case began in 1997, when Amgen filed a declaratory judgment suit against TKT. *Id.* at 146. A federal district court in Boston, Massachusetts, ruled that three of the main patents of Amgen were valid and infringed by TKT. *Id.* at 165. On appeal by TKT, the Federal Circuit affirmed a majority of the lower-court 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. *Amgen Inc. v. Hoechst Marion Roussel, Inc. (Amgen II)*, 314 F.3d 1313, 1358 (Fed. Cir. 2003). The district court recently addressed these issues on remand. *See Amgen, Inc. v. Hoechst Marion Roussel, Inc. (Amgen III)*, 339 F. Supp. 2d 202 (D. Mass. 2004). The ultimate result of this decision, coupled with the district court's earlier decisions, is that the four Amgen patents at issue have been held valid, enforceable, and infringed by TKT. *Id.* at 336.

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 DNA sequences does not impel us to accept TKT’s position when the asserted claims do not contain such an express limitation.²⁷²

Thus, despite differences in Amgen’s EPO product and TKT’s GA-EPO, the Federal Circuit refused to limit the scope of Amgen’s asserted claims.²⁷³ Although TKT was found to not literally infringe the ’080 patent,²⁷⁴ because 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, GA-EPO was found to infringe under the doctrine of equivalents.²⁷⁵

A broad comparison between the U.S. and U.K. positions demonstrates that not only is the process of assessing legal viability rather complex, but also that the results of such assessment would vary across jurisdictions.

b. Research Exemption

In addition to determining patent 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 would infringe. This would be particularly true in situations where one cannot create the substitute without working with the patented gene in question.²⁷⁶

This is where a robust research exemption helps. Such an exemption exists in most patent regimes and is an important tool that guarantees a certain amount of flexibility for using the patented invention in working towards a downstream product.²⁷⁷ Unfortunately,

272. *Amgen II*, 314 F.3d at 1326.

273. *See id.* at 1327.

274. U.S. Patent No. 5,621,080 (filed June 6, 1995) (issued Apr. 15, 1997). In April 1997, when Amgen initially filed against TKT for a declaratory judgment of infringement, three patents were at issue, including the ’080 patent. *Amgen III*, 339 F. Supp. 2d at 213. However, in October 1999, Amgen amended its complaint to include infringement of two additional patents that were issued after the initial complaint. *Id.*

275. *Amgen I*, 126 F. Supp. 2d at 133. The Federal Circuit vacated and remanded this finding of equivalent infringement on other technical grounds. *Amgen II*, 314 F.3d at 1345. The district court has since reaffirmed its finding. *See Amgen III*, 339 F. Supp. 2d at 220–21.

276. Such infringements, however, are difficult to detect. *See Walsh et al., supra* note 10, at 328 (suggesting that such difficulty in detection contributes to the development of working solutions); *see also supra* text accompanying note 49.

277. *See JOHN R. THOMAS, SCIENTIFIC RESEARCH AND EXPERIMENTAL USE PRIVILEGE IN PATENT LAW 1–2, 20 (2004), available at <http://www.fas.org/sfp/crs/RL32651.pdf>; see also Patents Act, 1977, c. 37, § 60(5)(b).*

the scope of exemption is limited, particularly in the context of those gene patents that qualify as research tool patents.²⁷⁸

2. *Technical Viability*

After having determined that the alternative or substitute is legally viable, one ought to assess its technical viability. As stated in Part II, 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 pharmaceutical firm representative: “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.”²⁷⁹

Similarly, although substituting the gene of a nematode worm or a chimpanzee for the patented human BRCA gene (as proposed in Part II) could work for researchers trying to define the function of the corresponding protein, such substitutions may not be of much help in the context of “a clinical test that has a direct and immediate use for patients.”²⁸⁰

3. *Economic Viability*

If the alternative in question passes the above two thresholds, it still has to clear the economic viability hurdle—perhaps the most complex 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.²⁸¹

278. See *supra* text accompanying note 28.

279. Walsh et al., *supra* note 10, at 314 n.43.

280. E-mail from Arupa Ganguly, Associate Professor, Univ. of Pa., to author (Jan. 4, 2005) (on file with author). Dr. Ganguly’s lab in the Department of Genetics was one of the many that had to discontinue diagnostic testing for breast cancer owing to Myriad’s patents covering the breast cancer genes and diagnostic testing methods. See Borger, *supra* note 44.

281. See *supra* Part III.C.2.

Given the high costs inherent in any biopharmaceutical research and development, one of the more definite factors to take into consideration could be the financial viability of an alternative.²⁸² For example, President Bush's decision to deny federal funding to human embryonic cell lines created after August 9, 2001,²⁸³ limited the ability of researchers to procure financing and thereby, to invent around the stem cell patents owned by the Wisconsin Alumni Research Foundation (WARF).²⁸⁴

C. Jurisdiction- and Time-Specificity of Viability

As the above analysis demonstrates, the issue of viability is jurisdiction-specific—while a substitute may be viable in one jurisdiction, it may not be in another. The Amgen case is a good example, with TKT's technology being viable in the United Kingdom but not in the United States.

Similarly, a determination of viability is also time-specific. With scientific progress and an increase in the prospects of inventing around, a non-viable substitute today could turn out to be viable tomorrow. Similarly, changes in the law could impact the issue of viability considerably.

V. CONCLUSION

*"A knot!" said Alice, always ready to make herself useful, and looking anxiously about her. "Oh, do let me help to undo it!"*²⁸⁵

I began this journey by exploring ways to resolve the blocking impasse in the biopharmaceutical arena. In the process, however, an even knottier issue arose: whether patented genes blocked downstream research in the first place. Without in any way claiming to have solved this conundrum, I do hope I have provided a useful framework for assessing the existence of blocking.

To this end, I question the assumption that patented genes cannot be invented around and that there are no alternatives or substitutes. Having said this, it is important to bear in mind that the key issue is not merely the theoretical possibility of such alternatives, but whether such

282. "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." Wolf & Murakami, *supra* note 178, at 151.

283. 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 Walsh et al., *supra* note 10, at 333 n.66.

284. The patents held by 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 tissue types. See *id.* at 308.

285. LEWIS CARROLL, ALICE'S ADVENTURES IN WONDERLAND 38 (HarperCollins 1992) (1865).

alternatives are viable. To compute such viability, I draw on the doctrine of essential facilities, a competition law concept that is becoming increasingly popular in Europe. In particular, one of the prongs of this doctrine—namely, essentiality—is useful to generate a framework to determine the viability of alternatives to patented genes.

An application of such framework to patented genes would help generate data that could then be used to determine the existence and extent of blocking in the biopharmaceutical sector. This could in turn help decide whether blocking or restricted access is of such a widespread nature as to warrant a substantial legal and institutional response.