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Debra L. Greenfield

Institute on Biotechnology and the Human Future

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Greenberg v. Miami Children's Hospital: Unjust Enrichment and the Patenting of Human Genetic Material

*Debra L. Greenfield, J.D.**

I. INTRODUCTION

The complete sequencing of the human genetic code offers numerous opportunities for scientific progress and advancements in medicine. However, genetics has become not only a vast scientific enterprise, but a commercial one as well, supported by the ability of both purely scientific researchers, as well as biotechnological firms to procure patents on these gene sequences. These patents often result in restrictions upon the use of genome sequences. The practice of patenting human genetic material within the context of medical research and human health care is being fiercely critiqued and raises diverse ethical, social, and political objections.¹ Additionally, critics are finding evidence suggesting that the status and practice of patenting human genetic material is creating numerous limitations on scientific progress in the areas of biomedical research and human health care and should be subject to reform.² In light of these concerns, controversies will materialize from the ensuing “gold rush”³ on

* Ms. Greenfield is an attorney practicing in the area of bioethics and is a fellow with the Institute on Biotechnology and the Human Future.

1. See, e.g., Melissa L. Sturges, Note & Comment, *Who Should Hold Property: Rights to the Human Genome? An Application of the Common Heritage of Humankind*, 13 AM. U. INT'L L. REV. 219 (1997). See also Jonathan Kahn, *What's the Use? Law and Authority in Patenting Human Genetic Material*, 14 STAN. L. & POL'Y REV. 417 (2003).

2. See, e.g., Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, SCIENCE, May 1, 1998, at 698; Lori B. Andrews, *The Gene Patent Dilemma: Balancing Commercial Incentives with Health Needs*, 2 HOUS. J. HEALTH L. & POL'Y 65, 66-67 (2002); Laurie L. Hill, *The Race to Patent the Genome: Free Riders, Hold Ups and the Future of Medical Breakthroughs*, 11 TEX. INTELL. PROP. L. J. 221, 245-46 (2003); Sheldon Krimsky, *The Profit of Scientific Discovery and Its Normative Implications*, 75 CHI.-KENT L. REV. 15 (1999).

3. See LORI ANDREWS & DOROTHY NELKIN, *BODY BAZAAR: THE MARKET FOR HUMAN TISSUE IN THE BIOTECHNOLOGY AGE* 42 (2001) (characterizing the commercialization of the human genome as such).

the use of human genetic material, as both individuals as well as societal groups challenge the practice and its effects.

One recently decided case arguably provides a broad and far-reaching *legal* theory and basis upon which the critics of human gene patents can rely. The common law cause of action for unjust enrichment provides a precedent for challenging the commercialization and patenting of human genetic material given to researchers for the purpose of discerning medical and scientific knowledge meant to benefit society at large. *Greenberg v. Miami Children's Hospital Research Institute, Inc.*⁴ involved subjects who instigated research to isolate the gene for Canavan disease and who for numerous years supplied vital and critical materials and resources for the investigation. The subjects were unaware of the doctors' and hospitals' intentions to commercialize the fruits of the work. Six claims were alleged, including breaches of informed consent and fiduciary duties, fraudulent concealment, conversion, and misappropriation of trade secrets.⁵ Count III of the complaint alleged that the defendants had been "unjustly enriched" by their actions in patenting, licensing, and restricting the use of the gene. This was the only claim to survive the defendants' motions to dismiss.⁶

The surviving cause of action for unjust enrichment suggests broad implications beyond the narrow reading of the facts of the case. By examining the cause of action, including its conceptual underpinnings and its application in *Greenberg*, it can be seen as a possible tool for plaintiffs contesting the patenting of human genetic material or questioning its effects. Where the finding of an inequity is the basis for the legal argument, it is also possible to identify inequities that support the ethical, social, scientific, and political critiques against human gene patenting. By adhering to its traditional roots as a "flexible, broad-based theory"⁷ and by finding numerous analogies within the current law, unjust enrichment provides one legal alternative as a rationale for necessitating changes in policy dealing with the patenting of human genetic material.

II. UNJUST ENRICHMENT: THE CAUSE OF ACTION

The legal concept of restitution has both remedial and substantive aspects. It exists within the traditional contract and tort framework,

4. *Greenberg v. Miami Children's Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064, 1066 (S.D. Fla. 2003).

5. *Id.* at 1068.

6. *Id.* at 1073.

7. See Candace Saari Kovacic-Fleischer, *Forum: Restitution In Public Concern Cases*, 36 LOY. L.A. L. REV. 901 (2003) (discussing the use of unjust enrichment in cases of public concern such as lead, tobacco, asbestos, etc.).

wherein a breach may give rise to a remedy based upon restitution when, as a consequence of that breach, the defendant has been unjustly enriched. Substantive restitution, commonly known as “unjust enrichment” is a separate cause of action and exists wholly independent of tort or contract. Varying terms are also used to describe the cause of action, such as “quasi-contract,” or the older “monies had and received” or “restitution to prevent unjust enrichment” in the reported cases.”⁸ Although imprecision has resulted from overlapping definitions and descriptions, the basic underlying principles retain broad acceptance.

The fundamental precepts include: “[a] person who has been unjustly enriched at the expense of another is required to make restitution to the other,”⁹ and “[a] person is enriched if he has received a benefit, and a person is unjustly enriched if the retention of the benefit would be unjust.”¹⁰ These principles lack precise definitions and scholars continue to debate their exact meaning.

The most widely cited and discussed view associates unjust enrichment with a notion of equity in the broadest sense.¹¹ In eighteenth century England, Lord Mansfield explained that “the gist of this kind of action is, that the defendant, upon the circumstances of the case, is obliged by the ties of natural justice and equity to refund the money.”¹² The quote identifies “a substantial tradition in English and American law of referring to unjust enrichment as if it were something identifiable *a priori*, by the exercise of a moral judgment anterior to legal rules.”¹³ Justice Cardozo echoed this traditional view in American law, writing that the test was whether a benefit “was received in such circumstances that the possessor will give offense to equity and good conscience if permitted to retain it.”¹⁴ A recent description

8. See *Equilease Corp. v. Lando*, 634 F.2d 850, 853 (5th Cir. 1981).

9. RESTATEMENT (FIRST) OF RESTITUTION: UNJUST ENRICHMENT §1 (1937) [hereinafter RESTATEMENT FIRST]; see also RESTATEMENT (THIRD) OF RESTITUTION & UNJUST ENRICHMENT §1 (Discussion Draft 2000) [hereinafter RESTATEMENT THIRD].

10. RESTATEMENT FIRST, *supra* note 9, §1 cmt. a.

11. See, e.g., *Equilease Corp.*, 634 F.2d at 852 (stating “[b]y whatever its name the theory of recovery is a creature of equity and governed by principles of equity.”); *Tooltrend Inc. v. CMT Utensili, SRL*, 198 F.3d 802, 805 (11th Cir. 1999) (noting “[a] claim of unjust enrichment is an equitable claim based on a legal fiction created by courts to imply a ‘contract’ as a matter of law.”). See also *Kovacic-Fleischer*, *supra* note 7, at 901 (“The plaintiffs use, either explicitly or implicitly, the broad concept of restitution found in section one of the Restatement of the Law of Restitution.”).

12. See Emily Sherwin, *Restitution and Equity: An Analysis of the Principle of Unjust Enrichment*, 79 TEX. L. REV. 2083, 2087 (2001) (quoting *Moses v. Macferlan*, 97 Eng. Rep. 676, 681 (K.B. 1760)).

13. RESTATEMENT THIRD, *supra* note 9, §1 cmt. b.

14. DOUGLAS LAYCOCK, *MODERN AMERICAN REMEDIES* 525 (2d ed. 1994) (citing *Atlantic Coast Line R.R. v. Florida*, 295 U.S. 301, 309 (1935)).

of this interpretation of the claim calls it “a direct appeal to a standard of equitable and conscientious behavior as a source of obligations that society will enforce with a legal sanction.”¹⁵

This broad reading has historically given a “gap-filling”¹⁶ character to the cause of action, where neither tort, contract, nor property theories were appropriate. The theory was thus applied in situations that could not be enumerated exhaustively. Claims of unjust enrichment easily exist when a defendant unlawfully acquires a benefit from the plaintiff. Furthermore, a defendant may be unjustly enriched without having committed any other civil wrong. This can occur when one is enriched by accepting mistaken payments or improvements or through another’s discharge of a joint obligation.¹⁷ A defendant who benefits from the unauthorized use of his neighbor’s goods may be liable for unjust enrichment regardless of whether he would be liable for conversion.¹⁸ Scenarios giving rise to defenses against contract enforcement, such as undue influence, duress or the abuse of position may be the basis of the claim,¹⁹ or when passive acceptance of a benefit would be deemed unconscionable.²⁰ Despite current suggestions to narrow the principle as an aid to predictability,²¹ cases of unjust enrichment often resist classification. Instead, they can be understood simply as instances of equitable decision-making, where the defendant gains at the plaintiff’s expense.²²

15 RESTATEMENT THIRD, *supra* note 9, § 1 cmt. b.

16. David N. Fagan, Note, *Achieving Restitution: The Potential Unjust Enrichment Claims of Indigenous Peoples Against Multinational Corporations*, 76 N.Y.U. L. REV. 626, 629 (2001) (noting “[u]njust enrichment originated as a theory of recovery in order to fill gaps left uncovered by traditional legal categories, such as contract, tort and property law”).

17 JAMES FISCHER, UNDERSTANDING REMEDIES 304 (1999).

18 RESTATEMENT (SECOND) OF RESTITUTION § 45(2) (Tentative Draft No. 2, 1984).

19. RESTATEMENT (SECOND) OF RESTITUTION §1 cmt. b (Tentative Draft No. 1, 1983).

20. FISCHER, *supra* note 17, at 304 (citing *Zoppo v. City of Manchester*, 453 A.2d 1311, 1313 (N.H. 1982)).

21. See RESTATEMENT THIRD, *supra* note 9, § 1 cmt. b (distinguishing “unjust enrichment” from the narrower doctrine of “unjustified enrichment,” in which the enrichment lacks an adequate legal basis and generally results from a transfer that the law deems ineffective in altering ownership rights. Since legally effective transfers result based on a consensual exchange, a valid gift, or a legal duty, “the concern with restitution is predictably with those anomalous transfers that cannot be justified by the terms of a valid and enforceable exchange transaction; by the intention of the transferor to make a gift; or by the existence of a legal duty to the transferee.”).

22 See *Sherwin*, *supra* note 12, at 2089-90 (discussing *Sharp v. Kosmalski*, 351 N.E.2d 721 (N.Y. 1976) and *Kossian v. Am. Nat’l Ins. Co.*, 254 Cal. App. 2d 647 (1967). *Sharp* found “equity should intervene” when the promise to give a companion/caregiver a farm as a substitute for marriage was revoked. *Sharp*, 351 N.E.2d at 123. In *Kossian*, a bankrupt motel owner failed to pay a cleaner for her services and the subsequent owner then took possession of the clean premises and collected on insurance for the cost of cleaning the property. *Kossian*, 254 Cal. App. 2d at 648. Thus, the court found the double

The decisional framework thus denotes flexibility and the cause of action has been used to provide “new solutions to old problems.”²³ It has additionally been seen as having the potential to address novel societal problems in changing times.²⁴ In cases of first impression, such as *Greenberg*, or in future cases such as those dealing with the patenting of human genetic material for commercial gain, it is arguable that the scope of the claim will enable findings of unjust enrichment. This is especially true where courts adhere to the traditional roots grounded in broad concepts of equity.

III. UNJUST ENRICHMENT: THE PRIMA FACIE CASE

Although the test might have variations depending on a particular jurisdiction, the following elements need to be proven in a prima facie case. These elements are: a benefit conferred upon the defendant by the plaintiff; awareness, appreciation, or knowledge by the defendant of the benefit; and acceptance or retention of the benefit by the defendant under such circumstances as to make it inequitable for the defendant to retain the benefit without payment to the plaintiff.²⁵

A. The Nature of a Benefit:

The concept of benefit is broad and encompassing. A person confers a benefit if he gives possession of or an interest in money, land, or chattels. Conferral also occurs if he performs services beneficial to or at the request of the other, satisfies a debt or a duty to the other, or in any way adds to the other's security or advantage. It has been generally stated and consistently understood that the word benefit denotes “any form of advantage.”²⁶

Furthermore, an individual “confers a benefit not only where he adds to the property of another, but also where he saves the other from expense or loss.”²⁷ In the context of patents on human genetic material, a benefit is realized when the acquisition of genetic material constitutes a “saving” to

indemnification against “equitable principles of unjust enrichment.” *Id.* at 651.).

23. See Fagan, *supra* note 16, at 629 (citing JACK BEATSON, *THE USE AND ABUSE OF UNJUST ENRICHMENT: ESSAYS ON THE LAW OF RESTITUTION* 209 (1991)).

24. See Kovacic-Fleischer, *supra* note 7, at 901 (discussing the potential use of the claim for addressing harms done to large populations including: corporate corruption, tobacco, asbestos, lead, and water pollution).

25. See *Greenberg v. Miami Children's Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064, 1072 (S.D. Fla. 2003) (citing *Tooltrend, Inc. v. CMT Utensili SRL*, 198 F.3d 802, 805 (11th Cir. 1999) and *Duncan v. Kasim, Inc.*, 810 So. 2d 968, 971 (Fla. Dist. Ct. App. 2002)).

26. LAYCOCK, *supra* note 14, at 527.

27. FISCHER, *supra* note 17, at 303 (quoting *Chem. Bank v. Wash. Pub. Power Supply Sys.*, 691 P.2d 524, 544 (Wash. 1984)).

potential defendants involved in profiting from the use of such material. In the *Greenberg* case, the molecular biologist identifying the Canavan gene²⁸ discussed how the use of particular genetic material provided such savings to the research institution attempting to isolate the gene:

Obtaining the Dor Yeshorim samples saved us and MCH (Miami Children's Hospital) a tremendous amount of time in our research. It would have taken us and MCH years to collect that many samples from Ashkenazi Jewish individuals. Instead the whole process was completed in six months Obtaining the . . . samples saved us and MCH millions of dollars in expenses to identify . . . and obtain samples. In addition . . . I would estimate that the value of each of these blood samples would have themselves been at least \$150.00 to \$250.00.

The blood, tissue and other samples that were provided to us by families with the Canavan gene mutation . . . were worth far more than \$200.00 a sample. In fact, the values of the samples is difficult, if not impossible to measure because they were indispensable to our research and not readily available to us from any other source.²⁹

Genetic material obtained by research institutions or biotechnology corporations can thus be considered a benefit or a form of advantage, regardless of whether consent was obtained or whether the process involved "adding to the property of another" or "saving another from expense or loss."³⁰

This particular concept of benefit has also been used to apply theories of unjust enrichment to controversies of public concern,³¹ such as class action cases involving tobacco,³² lead,³³ guns,³⁴ asbestos, and water pollution.³⁵ These cases involve dangerous products, where the sellers have misled the public or avoided expenses that would make the product or its disposal safer, and "all seek disgorgement of what the defendant has gained or saved

28 See Rajinder Kaul Aff. 12-16, *Greenberg v. Miami Children's Hosp. Research Inst., Inc.*, (S.D. Fla. 2003) (No. 02-22244-Civ-Moreno).

29 *Id.*

30 RESTATEMENT FIRST, *supra* note 9, § 1 cmt. b.

31 See Kovacic-Fleischer, *supra* note 7, at 905.

32 *Allegheny Gen. Hosp. v. Philip Morris, Inc.*, 228 F.3d 429, 446-47 (3d Cir. 2000).

33 See, e.g., *State v. Lead Indus. Ass'n.*, No. 99-5226, 2001 R. I. Super. LEXIS 37 (R.I. Super. Ct. 2001); *City of New York v. Lead Indus. Ass'n.*, 222 A.D.2d 119 (N.Y. App. Div. 1996).

34 See, e.g., *City of Boston v. Smith & Wesson Corp.*, 12 Mass. L. Rep. 225 (Mass. Super. Ct. 2000); *White v. Smith & Wesson Corp.*, 97 F. Supp. 2d 816 (N.D. Ohio 2000).

35 *Branch v. Mobil Oil Corp.*, 778 F. Supp. 35 (D. Okla. 1991).

by not reimbursing harm caused by the products put into commerce.”³⁶

In such cases, motions to dismiss fail in the face of general principles of restitution,³⁷ which recognize the “the unjustness of a company’s failure to ‘internalize externalities.’”³⁸ These cases are potentially of great interest with regard to the benefit analysis in future cases of unjust enrichment and the patenting of human genetic material. Whether, as in the *Greenberg* case, the specific harm of secret patenting occurs³⁹ or whether the harms created by the exclusionary patenting of human genetic material are generic, a duty to abate the potential costs of these harms could potentially be established by these precedents. Where profits made by those utilizing human gene patents result from the potential defendants avoiding the internalization of the costs of such patenting, these savings potentially represent a benefit in terms of the cause of action.

Historically, a claim of unjust enrichment required that the enrichment of the defendant be at the expense of or cause detriment to the plaintiff.⁴⁰ However, this requirement has been generally rejected and today a defendant may be unjustly enriched where he realizes a benefit even if the plaintiff has not suffered an actual loss or a corresponding equal loss.⁴¹

The concept has significance not only when a benefit is acquired through a “wrongful transfer,” but also where gain or profits are obtained independent of a transfer. Recent cases dealing with corporate corruption

36. Kovacic-Fleischer, *supra* note 7, at 913. In the gun cases, the plaintiff cities were found to be paying the costs of the defendants’ “externalities,” i.e., the costs of failing to incorporate safety devices into the guns and negligent market practices. Thus, these savings to the manufacturers were found to be a benefit. In cases dealing with costs related to lead or lead paint, where the defendants were not paying for the damages associated with the lead or lead products, the “States’ lead-related expenditures” added to the defendants’ advantage or saved them from loss.

37. *Id.* at 913, 918-20 (“It must be noted . . . that plaintiffs do not survive motions to dismiss in the majority of dangerous product restitution cases.”) One dangerous products case, *Allegheny Gen. Hosp.*, 228 F.3d at 446 (3d. Cir 2000) (citing *Steamfitters Local Union No. 420 Welfare Fund v. Phillip Morris, Inc.*, 171 F.3d 912, 936-37 (3d. Cir 1999)) found there was no duty for a tobacco company to pay for the resultant health care costs. In the same case, the court also discussed the remoteness of the harm of the product in reasoning that the alleged benefit to the tobacco company was not unjust.

38. Kovacic-Fleischer, *supra* note 7, at 913.

39. See *Greenberg v. Miami Children’s Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064 (S.D. Fla. 2003).

40. FISCHER, *supra* note 17, at 317 (citing GEORGE PALMER, *LAW OF RESTITUTION* § 2.6 (1978)).

41. *Id.* (citing PALMER, *supra* note 40, at § 2.10; *RESTATEMENT FIRST* § 150 (1937)). In *Edwards v. Lee’s Admin.*, 96 S.W.2d 1028 (Ky. Ct. App. 1936), an underground cave was developed as a tourist attraction by the defendant, where an inaccessible one-third of the cave was owned by the plaintiff. In that case, profits received, rather than sustained damages, was the basis for recovery in unjust enrichment.

and insider trading provide illustrations of this phenomenon.⁴² The idea that gain need not correspond with a loss, as well as the possibility that no transfer has occurred, might be particularly useful to a claim of unjust enrichment in the basic context of patenting human genetic material. Where any *specific* detriment might be too attenuated or difficult to quantify, a distinctive feature of the remedy is that liability is based on and recovery is usually measured by the benefit to the defendant rather than the plaintiff's loss.

In situations where the benefit has been provided, issues arise as to whether the benefit must be conferred under circumstances that created an expectation of payment or compensation on the plaintiff's part. When goods or services are provided for the plaintiff's own benefit to obtain a business advantage, for example, no unjust enrichment exists.⁴³ Although some courts require this expectation, some limit it to actions of quasi-contract.⁴⁴ Others do not require it as part of the *prima facie* case. Clearly, some circumstances oftentimes do not require such an expectation, such as when property is given as a gift by mistake. In any of these situations, courts may find the question relevant as to whether the retention of the benefit would be considered inequitable.⁴⁵

The general limiting principle of the broad interpretation of a "benefit" reiterates this theme, where the terms "volunteer" or "officious intermeddler" are used to justify a denial of an unjust enrichment claim.⁴⁶ It is difficult to surmise what "officiousness" is from definitional standards. The Restatement of Restitution provides that "officiousness means interference in the affairs of others not justified by the circumstances under which the interference takes place."⁴⁷ Courts have clarified its meaning,

42. Kovacic-Fleischer, *supra* note 7, at 909-15 (discussing *Newby v. Enron Corp.*, 18 F. Supp. 2d 684, 692 (S.D. Tex. 2002); *SEC v. Yun*, 148 F. Supp. 2d 1287, 1292 (M.D. Fla. 2001)). In *SEC v. Yun*, only the tippee and not the tipper profited from an illegal, inside trade, yet the court found these profits could be disgorged jointly and severally. The court presumed that even where the gain was potential, rather than actual, the defendant had received an "intangible unjust enrichment from the insider trading scheme" where no actual transfer had occurred and no corresponding loss had ensued.

43. *See, e.g., Tooltrend, Inc. v. CMT Utensili SRL*, 198 F.3d 802, 807 (11th Cir. 1999).

44. FISCHER, *supra* note 17, at 310-11 (citing *Yoh v. Daniel*, 497 S.E.2d 392, 394 (Ga. Ct. App. 1998) and noting that a claim for unjust enrichment does not require a showing of the anticipation of compensation).

45. *Id.* at 311. In the *Tooltrend* case, two companies sold identical products with the same name after the distribution agreement disintegrated. The plaintiffs alleged that their advertising and promotion costs would be an unjust benefit to the other company if that company was declared the rightful owner of the name. The court reasoned, however, that the plaintiffs were only advertising and promoting to make a profit, thus it was not considered an inequitable retention of a benefit.

46. *See* FISCHER, *supra* note 17, at 305.

47. RESTATEMENT FIRST, *supra* note 9, § 2.

such as the Idaho state appellate court which defines officiousness as characteristic of "a person who, without request, at his own insistence, and without a valid reason, confers a benefit upon another [and thus] is not entitled to restitution."⁴⁸

Cases reflect the volunteer-officious meddler principles. One acting to protect his own legal interests, even where no legal liability exists, is not a volunteer. An example would be an insurance company making a settlement payment when it is potentially liable for a claim, even though the claim is nonexistent.⁴⁹ One who acts out of a legal obligation is similarly not deemed to be a volunteer.⁵⁰ However, an individual motivated by a moral, rather than legal, duty or desire to protect his own interests is usually described as a volunteer. Rescuers are thus considered volunteers. However, recovery is not precluded where one *mistakenly* believes one has a moral obligation to act and does so.⁵¹

This limiting principle is arguably a possible defense in litigation regarding the harms and effects of patenting human genetic material.⁵² Giving one's tissue for the cause of medical research implicates the volunteer principle. However, proof of donative intent could be required to support the giving of a benefit as a "gift." Where the genetic material has been given without consent or without knowledge that the practice of patenting will result in profit to the defendant, the question of whether the conferral of the benefit was done voluntarily or as the result of officious intermeddling is raised.

B. An Inequitable or Unjust Retention of the Benefit:

The third element of the cause of action provides the critical issue in

48. FISCHER, *supra* note 17, at 305 (citing *Curtis v. Becker*, 941 P.2d 350, 354 (Idaho Ct. App. 1997)).

49. *See id.* at 306 (discussing *Perkins V. Worzala*, 143 N.W.2d 516, 518 (Wis. 1966)).

50. *Id.* (discussing *In re Monarch Capital Corp.*, 163 B. R. 899, 908 (Bankr. D. Mass. 1994)). In *Monarch Capital*, a business broker called a prospective buyer regarding the debtor's subsidiary after an involuntary bankruptcy petition had been filed against a debtor. The call led to the sale. The court held that the broker was entitled to restitution for his post-petition services because he was bound by his pre-petition contract with the debtor, yet he was unable to obligate the bankrupt estate under contract to do anything other than pay expenses incurred after the bankruptcy was ordered.

51. *See* FISCHER, *supra* note 17, at 307-08 (discussing *Deskovick v. Porzio*, 187 A.2d 610 (N.J. Super. Ct. App. Div. 1963), wherein the court found unjust enrichment had occurred when children paying their father's hospital bills based on the mistaken belief that he could not afford to pay them).

52. *See, e.g., Greenberg v. Miami Children's Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064, 1073 (S.D. Fla. 2003) ("Defendants contend . . . furthermore, the Plaintiffs received what they sought-the successful isolation of the Canavan gene and the development of a screening test.").

cases of the unjust enrichment claim. This issue is “identifying those forms of enrichment that the law treats as ‘unjust’ for purposes of imposing liability.”⁵³ The scope of the equitable principle is that the retention of a benefit is unjust when it violates the fundamental principles of justice, equity and good conscience.⁵⁴ It is difficult to draw bright lines and the decision-making is fact-specific: “everything depends on the circumstances of the individual case.”⁵⁵ Thus, divergent rationales emerge in the cases, which follow the fundamental principles, but also reveal how these concepts of fairness and justice are malleable and amorphous. These scenarios provide analogies and possible precedents for finding that the retention of a benefit in cases dealing with patenting human genetic material is inequitable where the legality of obtaining a patent does not preclude the possibility of an unjust enrichment.⁵⁶

Broad considerations of morality often provide a rationale for fulfilling the third element of the claim in cases dealing with cohabitation scenarios.⁵⁷ A similarly broad and amorphous rationale for the finding of an inequity is found in cases where windfalls have similar moral underpinnings.⁵⁸ Windfalls include the issuing of overpayments.⁵⁹ These cases are not precise as to why the retention of a windfall is specifically unjust. Instead, they are stated as innate and presumptive, illustrating that the enrichment can be legally justifiable but nonetheless considered unjust.⁶⁰ Thus, broad and traditional notions of equity inform the determination of whether the retention of a benefit is unjust. It is often the case that only considerations

53. RESTATEMENT THIRD, *supra* note 9, § 1 cmt. b.

54. *Greenberg*, 264 F. Supp. 2d at 1072.

55. *Moore Handley, Inc. v. Major Realty Corp.*, 340 So. 2d 1238, 1238 (1976).

56. *See Chou v. Univ. of Chicago*, 254 F.3d 1347, 1363 (Fed. Cir. 2001) (recognizing claim for unjust enrichment in context of gene patent dispute).

57. *See, e.g., Sharp v. Kosmalski*, 351 N.E.2d 721 (N.Y. 1976); *Kozlowski v. Kozlowski*, 395 A.2d 913, 916-18 (N.J. Super. Ct. Ch. Div. 1978). In *Kozlowski*, the judge asked: “Is there any remedy available under our law for a woman who has devoted 15 or more years living with a man . . .” *Id.* at 916. The court noted that “quasi-contract is . . . a legal concept rationalizing a sanction to prevent unjust enrichment based upon the equitable principle that whatsoever it is certain that a man ought to do, the law supposes him to have promised to do.” *Id.* at 918.)

58. *See Saporta v. Saporta*, 766 So. 2d 379, 381 (Fla. Dist. Ct. App. 2000) (recognizing, upon divorce, an implied promise that a home bought with funds that were previously transferred between husband and wife prior to marriage would be for the family and that if a constructive trust of the house was not given to the woman, the resultant windfall for the husband would amount to an unjust enrichment).

59. *See, e.g., Sharff, Wittmer & Kurtz, P. A. v. Messana*, 581 So.2d 906, 907-8 (Fla. Dist. Ct. App. 1991).

60. *Id.* at 907 (reviewing a claim of unjust enrichment where plaintiff received payments from a settlement agreement from a negligently prepared tax form, as well as an IRS payment resulting from the negligence).

of 'good conscience' would disallow the retention of the benefit.

In potential cases of unjust enrichment and the patenting of human genetic material, the existence of a patent oftentimes creates and allows for windfalls. Although there is an incentive system in individual cases, profits arising from patents are not necessarily tied to effort. Thus, the retention of the profits arising from these patents potentially creates an inequity which could be considered to be unjust. An irretrievable loss to a plaintiff can also be determinative in establishing that the retention of a benefit is inequitable.⁶¹ When a patent on human genetic material results in the gene's exclusive use or restricts it through licensing, an irretrievable loss has occurred.

More specific rationales also exist as the basis for fulfilling the third element of the prima facie case. In past cases, unjust enrichment was found when excessive profits have resulted in the finding of inequity. For example, overcharging residents of a nursing home constituted overreaching and "would equitably require the return of excess payments made."⁶² Where contracts are non-existent, the use of overreaching to describe excessive relies upon an unstated concept of equity. Illustrated in *Hall v. Humana Hospital*, plaintiffs brought a class action suit to recover alleged overcharges for pharmaceuticals and medical supplies and pled both common law and statutory counts of unjust enrichment.⁶³ Examples of these overcharges included a charge of \$11.50 for a single Zantac tablet, a charge of \$52.00 for one Tylenol with codeine, and a charge of \$20.50 for each individual Cipro tablet.⁶⁴

A case that was settled out of court provides a similar hypothetical in the area of pharmaceuticals, excessive profits, and unjust enrichment.⁶⁵ In 1989, Boots Pharmaceuticals commissioned Betty Dong, a clinical pharmacist, to compare its treatment for hypothyroidism, Synthroid, with cheaper alternatives made by other companies.⁶⁶ Synthroid had been used

61. See *Duncan v. Kasim*, 810 So. 2d 968, 971 (Fla. Dist. Ct. App. 2002) (holding that the inability to remove fixtures constituted unjust enrichment when plaintiff personally bore all expenses to improve a space in a lodge where she operated a bar although the management of the premises was illegal due to the fact that she was a convicted felon and the defendant appropriated all of the personal property).

62. See *Greenfield v. Manor Care Inc.*, 705 So. 2d 926, 931 (Fla. Dist. Ct. App. 1997).

63. See *Hall v. Humana Hosp.*, 686 So. 2d 653, 653 (Fla. Dist. Ct. App. 1996).

64. *Id.* at 655-58 (affirming the partial summary judgment for the defendants because the plaintiffs were not entitled to recover the alleged overcharges and because the payments which had been made resulted from a mistake of law concerning the enforceability of a previous contract made with the defendant).

65. See Michael Day, *He Who Pays the Piper*, NEW SCI. MAG., May 9, 1998, <http://www.newscientist.com/article/mg15821333.100> (discussing a suit where users of the drug Synthroid sued Knoll Pharmaceuticals).

66. *Id.*

by millions of patients and was the drug most recommended by physicians.⁶⁷ A complete switch to the less expensive brands would have saved the U.S. Health department \$365 million a year.⁶⁸ When the study showed that Synthroid was no better than the alternative drugs tested, the company that bought Boots, Knoll Pharmaceuticals, withdrew a paper that was about to be published in the Journal of the American Medical Association ("JAMA"), claiming the research was "fundamentally flawed."⁶⁹ The paper was finally published in JAMA in 1997 and the users of Synthroid sued Knoll, which settled out-of-court for \$98 million.⁷⁰ In future cases of patenting human genetic material, where pre-negotiated contracts are non-existent between the parties, principles of equity could determine that profits accrued from the patenting of human genetic material are excessive and that defendants have been overreaching.

Social and political motivations exist, described perhaps as public policy rationales, in many cases upholding claims of unjust enrichment under the federal Employee Retirement Income Security Act ("ERISA").⁷¹ In such cases, public health concerns result from the practice of patenting and profits accrued from the practice could be considered inequitable.

With potential implications for claims of unjust enrichment in the patenting of human genetic material, a federal district court decided a case of unjust enrichment within the specific context of the "secret" patenting of an invention.⁷² *University of Colorado Foundation v. American Cyanamid Company* specifically dealt with doctors who developed a method for reformulating prenatal supplements with the intent that the Cyanamid company would use their work to manufacture and profit from the sale of an improved product.⁷³ They also intended however, to publish their work, allowing other manufacturers of the product to use these findings.⁷⁴ The court found that "Cyanamid removed the reformulation technology from the free marketplace of ideas . . . thwarting what the doctors intended freely to convey, (namely) a complete and definite research idea for reformulating

67. *Id.*

68. *Id.*

69. *Id.*

70. *Id.*

71. *See, e.g.,* Metropolitan Life Ins. Co. v. Solomon, 996 F. Supp. 1473, 1475 (1998). *See also* Heller v. Fortis Benefits Ins. Co., 145 F.3d 487, 495 (D.C. 1998) (finding that a disability payment following a determination that Heller was not qualified to receive disability anymore constituted unjust enrichment and would "be a cost unfairly borne by the other members of the plan").

72. *See* Univ. of Colo. Found. v. Am. Cyanamid Co., 153 F. Supp. 2d. 1231 (D. Colo. 2001).

73. *Id.* at 1233-43

74. *Id.* at 1243.

prenatal supplements that would inure to the benefit of all . . . not just Cyanamid.”⁷⁵ The court thus held that “a defendant who uses a benefit provided by the plaintiff in an unauthorized and unfair manner may be liable in Colorado for unjust enrichment.”⁷⁶

Thus, a broad range of factual circumstances and varying rationales illustrates whether the retention of a benefit proves to be inequitable. Ascertaining equity might aid judges in particularizing justice and avoiding the application of rigid rules as a legal principle based on morality and fairness.⁷⁷ Either way, courts will continue to assess whether or not the retention of the benefit is unjust. The equitable nature of unjust enrichment will certainly be definitive in the context of arguments against the patenting of human genetic material. The case of *Greenberg* is indicative of its potentially far-reaching scope and broad application.

IV. UNJUST ENRICHMENT AND THE *GREENBERG* CASE

The original decision in *Greenberg*, which upheld the unjust enrichment claim, led to a settlement, although further rulings on the issue might have provided even more evidence and law to bolster the arguments against the commercialization of human genetic material through exclusive patenting rights. Nevertheless, the value of the practice by which these patents are obtained was clearly questioned in the decision, which concerned itself with “a tale of a successful research collaboration gone sour.”⁷⁸

The plaintiffs consisted of a group of parents whose children died from the rare genetic Canavan disease and various nonprofit organizations who had helped these parents in their endeavors to find a test and cure for the disease, including the Canavan Foundation, National Tay-Sachs and Allied Disease Association, and Dor Yeshorim, a group providing screening and counseling services to members of the Jewish community.⁷⁹ In 1987, Daniel Greenberg contacted Dr. Reuben Matalon, a co-defendant, and requested his assistance in locating the gene responsible for disease in order to develop both carrier and prenatal genetic testing.⁸⁰ The plaintiffs continuously provided Dr. Matalon with vital tissue samples, financial

75. *Id.* (citing *Univ. of Colo. Found. v. Am. Cyanamid Co.*, 974 F. Supp. 1339, 1354 (D. Colo. 1997) [hereinafter *Cyanamid III*]; *Univ. of Colo. Found. v. Am. Cyanamid Co.*, 105 F. Supp. 2d 1164, 1183 (D. Colo. 2000) [hereinafter *Cyanamid IV*]).

76. *Id.* at 1234.

77. *See* Sherwin, *supra* note 12, at 2085 (describing principles of equity as potentially derived from these three distinct philosophical and jurisprudential approaches).

78. *Greenberg v. Miami Children's Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064, 1066 (S.D. Fla. 2003).

79. *Id.* at 1067

80. *Id.* at 1066

support, and aid in identifying the location of Canavan families internationally, as well as creating a Canavan registry, a confidential database and compilation with critical epidemiological, medical, and other information about the families.⁸¹ The plaintiffs' understanding of the potential outcome of this collaboration was that any carrier or prenatal testing developed using such research would be provided on an affordable and accessible basis.⁸² The plaintiffs also expected that Matalon's research would remain in the public domain to promote the discovery of more effective prevention techniques and treatment and, eventually, to effectuate a cure for the disease itself.⁸³

In 1990, Matalon became associated with co-defendant Miami Children's Hospital and continued the relationship with the plaintiffs, accepting both tissue samples and financial support.⁸⁴ In 1993, Matalon and his team successfully isolated the gene responsible for Canavan disease. Buoyed by these findings, the plaintiffs continued to supply resources to the team.⁸⁵ In September 1994, the defendants submitted a patent application for the identified genetic sequence, as well as any related activities, including carrier and prenatal testing, gene therapy and other treatments, and research involving the gene and its mutations.⁸⁶ The patent was finally issued in 1997.⁸⁷ The plaintiffs alleged that they had no knowledge either of the plan to seek a patent, or the actual filing, and that they first were made aware of it in November 1998.⁸⁸ At that time, Miami Children's Hospital threatened to curb ongoing tests for Canavan disease through the use of restrictive licensing and the collection of royalty fees, thus increasing the cost of screening and limiting the number of laboratories that could perform the test.⁸⁹

The court did not grant a motion to dismiss the count of unjust enrichment after the complaint was viewed in the light most favorable to the plaintiffs.⁹⁰ The opinion in the case adheres to the traditional roots of unjust enrichment in its reasoning, finding that "the retention of the benefit violates fundamental principles of justice, equity and good conscience."⁹¹

81. *Id.* at 1067

82. *Id.*

83. *Id.*

84. *Greenberg*, 264 F. Supp. at 1067.

85. *Id.*

86. *Id.*

87. *Id.*

88. *Id.*

89. *Id.* at 1067-68

90. *Greenberg*, 264 F. Supp. at 1068-77.

91. *Id.* at 1072.

Although the Restatement was not cited, the outline of the discussion followed the definitional principle that “A person who has been unjustly enriched at the expense of another is required to make restitution to the other.”⁹²

The court quickly determined that a benefit had been conferred and acknowledged.⁹³ The defendants’ downfall, despite the assertion that the gene had been isolated and a test had been developed, was the unauthorized use of the benefit.⁹⁴ If the plaintiffs had known of the defendants’ intent to patent the genetic material, they would not have provided the benefit.⁹⁵ The defendants described the profits from the patenting as a “reimbursement” for the time and investment required by the research.⁹⁶ However, the judge felt that the plaintiffs could make the same claim and ruled that the retention of the benefit resulting from “a continuing research collaboration”⁹⁷ where “more than just a donor-donee relationship was alleged” is inequitable.⁹⁸

The brief and distinct conclusion relied on the broad equitable scope of unjust enrichment.⁹⁹ Considerations of fairness prevailed as the court refused to dismiss the claim based on the general context of the case, despite its rejection of the common law tort claims.¹⁰⁰ The “unauthorized” use of the genetic information was not found to be determinative of the other civil wrongs alleged in the case: lack of informed consent, fraudulent concealment, misappropriation of trade secrets, conversion, or breach of a fiduciary duty.¹⁰¹ Had liability been established in those contexts, restitution as a remedial response could have been imposed to prevent an unjust enrichment from occurring. The judge declined to extend a “duty of informed consent to the researcher’s economic interests”¹⁰² and yet the lack of disclosure to the plaintiffs of the defendants’ intent to patent and profit from the research was considered unjust.¹⁰³ Some undefined, inexplicable wrong had occurred at the plaintiffs’ expense and while it did not rise to the level of a tort because of the wrong, the retention of the profits could be

92. RESTATEMENT FIRST, *supra* note 9, §1 cmt. a.

93. *Greenberg*, 264 F. Supp. 2d at 1072.

94. *Id.*

95. *Id.*

96. *Id.*

97. *Id.*

98. *Id.*

99. *See Greenberg*, 264 F. Supp. 2d. at 1077.

100. *See id.*

101. *Id.*

102. *Id.* at 1070.

103. *Id.* at 1071.

considered inequitable.¹⁰⁴

The historic and traditional gap-filling nature of the substantive cause of action was visible in this case and thus significant for deciding future cases involving the patenting of human genetic material. Although the actual patenting of the genetic material was strictly legal, the denial of the contributions of the donors represented an injustice, the underlying basis for liability. Although certainly inconclusive and fact specific, the initial opinion represents an opening for challenges to the patenting of human genetic material even where the practice itself has been conducted within the confines of tort, contract, and property law.

Had the case proceeded to trial, certain defenses would have been predictable. One example involves invoking the general limiting principle and that the plaintiffs acted as volunteers or officious intermeddlers would have been suggested. The argument would assert that the conferral of the benefit arose from some general sense of duty, a donation unsolicited, derived from a moral, rather than legal obligation. Similarly, it might be suggested that a relevant consideration as to whether the retention of the benefit was unjust would be the question of whether in conferring the benefit, the plaintiffs had no expectation of payment or compensation in return and that they conferred the benefit gratuitously.

Thus, it has been posited that the case could have been decided within the narrower parameters of the cause of action as defined by the most recent edition of the Restatement of Restitution and Unjust Enrichment,¹⁰⁵ which concerns itself with the "anomalous transfers that cannot be justified by the terms of a valid and enforceable exchange transaction; by the intention of the transferor to make a gift; or by the existence of a legal duty to the transferee."¹⁰⁶ In hypothesizing a court's potential response, it would be difficult to qualify the conferral of the benefits as gifts or to surmise that the plaintiffs had no expectations in return for the conferral of tissue, money and time. Rather, the facts confirm that this was a collaborative research effort where the plaintiffs expected an affordable and accessible test for Canavan disease, as well as the possibility of continuing efforts to discover a cure.

Whatever the outcome might have been in this case, the law establishing the cause of action for unjust enrichment under these certain circumstances has great value as a precedent for those questioning the practice of patenting human genetic material for material gain. It is possible that parties who

104. *Id.* at 1073.

105. See Mary R. Anderlik & Mark A. Rothstein, *Canavan Decision Favors Researchers Over Families*, 31 J.L. MED. & ETHICS 450, 452 (2003).

106. *Id.* (citing RESTATEMENT THIRD, *supra* note 9, § 1 cmt. b).

would not have given their genetic material to researchers if they had known of the intent to patent and profit from such research, and such intent had remained undisclosed, could become potential plaintiffs. Additionally, parties who give their genetic material for the purpose of research in a collaborative effort and are excluded from the resulting fruits of the collaboration could sue the patent-holders. Under these circumstances, the retention of benefits could be considered inequitable under *Greenberg*. Furthermore, such a result could rest on the narrow distinction that these benefits were not merely gifts. Instead, broad, flexible, and far-reaching equitable principles inherent in the cause of action would dictate that an unjust enrichment had occurred.

V. THE EFFECTS OF PATENTS ON HUMAN GENETIC MATERIAL AND CLAIMS OF UNJUST ENRICHMENT

In considering the use of the claim of unjust enrichment within the context of patenting human genetic material, certainly the facts described in the *Greenberg* case are distinctive. The plaintiffs instigated the scientific research and continuously provided the genetic materials that eventually resulted in profits for the defendants.¹⁰⁷ Nonetheless, the rationale behind the claim's survival may provide a basis for legal challenges made by individual plaintiffs or classes of plaintiffs responding to the enrichment of those involved in the practice of patenting human genetic material. The practice could be challenged based upon the effects it has upon the dignitary concerns of individuals or groups in society: as an innately unfair societal, religious, or political construct. Another challenge could be that the effects of patenting human genetic material are detrimental to the health care of an individual or that it acts as an impediment to progress in medical research and gains in health care for the general public. In these situations, as well as in situations where an unauthorized use of human genetic material has occurred, unjust enrichment exists as a basis for liability.

A. The Effects of Human Genetic Material Patents and Human Dignity

Patent law is based upon a distinction between products that are man-made and those existing in nature.¹⁰⁸ The U.S. Supreme Court, in *Diamond v. Chakrabarty*, explained that "anything under the sun that is made by man" may be patented.¹⁰⁹ Starting in the 1990s, the first applications for patents based on human DNA were filed, followed by biotechnology firms

107. See *Greenberg*, 264 F. Supp. 2d at 1072-73.

108. See *Diamond v. Chakrabarty*, 447 U.S. 303, 308-09 (1980).

109. See *id.* at 309.

rushing to submit applications claiming DNA sequences.¹¹⁰ Critics charged that these patents were being granted too liberally. As a result, the U.S. Patent and Trademark Office (“PTO”) promulgated interim “Utility Guidelines” in December 1999, with a final that followed in January 2001 to assist in the evaluating the validity of patent applications.¹¹¹ The call for public comment on the proposed guidelines resulted in heated debates prompted by general concerns over the patenting of genetic material, human DNA in particular.¹¹²

The PTO responded unfavorably to arguments that genes were products of nature, and thus incapable of being patented.¹¹³ The agency found that “the inventor’s discovery of a gene can be the basis for a patent of the genetic composition isolated from its natural state and processed through purifying steps that separate the gene from other molecules naturally associated with it.”¹¹⁴ The PTO’s construction of this technical process “separates the genetic material itself from nature” and “draws the line between nature and artifice,” that is to say, what can be seen not as a scientific process, but a legal one.¹¹⁵ Thus, despite the fact that courts have determined that genetic material “is profoundly the essence of one’s human uniqueness,”¹¹⁶ patent law currently dictates that our genetic information is an object for commercialization.

Social norms provide broad arguments against such commercialization, wherein “human dignity is threatened precisely because it commodifies something that science tells us is essential to human identity.”¹¹⁷ In these

110. See Kahn, *supra* note 1, at 420-21. The article discusses arguments expressed during debates around proposed revisions to the Utility Guidelines issued by the U. S. Patent and Trademark Office (“PTO”) and argues that dignitary concerns were dismissed by the PTO in favor of market approaches. The article describes Craig Venter’s original application for over 6800 partial complementary DNA (cDNA) sequences called “express sequence tags” (ESTs), as well as subsequent applications from firms such as Celera Genomics (applications for over 20,000 gene sequences) and Incyte Genomics (holding patents for over 400 genes with applications pending, as of this writing, for another 10,000). The article states, “[c]urrently, over three million genome-related patent applications have been filed with the PTO,” citing U.S. Dep’t of Energy, Human Genome Project Information: Genetics and Patenting (2001), <http://www.ornl.gov/hgmis/elsi/patents.html>.

111. *Id.* at 417.

112. See *id.* at 421.

113. *Id.*

114. *Id.* at 426 (quoting Utility Examination Guidelines, 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001)).

115. *Id.*

116. Kahn, *supra* note 1, at 422 (quoting Moore v. Regents of the Univ. of Cal., 249 Cal. Rptr. 494, 508 (Cal. Ct. App. 1988)).

117. *Id.* at 423 (quoting Ted Peters, *Intellectual Property and Human Dignity*, in THE GENETIC FRONTIER: ETHICS, LAW, AND POLICY 215, 220-21 (Mark S. Frankel & Albert Teich eds., 1994) (arguing that notions of human dignity may discourage the patenting of human

discussions the gene is an embodiment of human identity while the patent, an incursion not unlike slavery, results in ownership rights of man's common heritage to either individuals or corporations.¹¹⁸

The patenting of human genes proves problematic for indigenous peoples who do not subscribe to Western notions of property, but instead view genetic identity as intrinsic to all peoples.¹¹⁹ According to a spokesperson, "[o]wnership is resisted not only in the name of the human subjects who supply the genetic material but also in the name of all generations, past and future, who are implicated, and hence somehow present in the germline."¹²⁰ Objections to the practice based on religious grounds also exist,¹²¹ as do generic social concerns. Human DNA is very much implicated in the "perennial moral concern in Western thought, whatever the ideological position of the thinker, about the commoditization of human attributes such as labor, intellect, or creativity, or, more recently, human organs, female reproductive capacity and ova."¹²²

These arguments did not hold great weight with the PTO, where the purification and isolation techniques sever human genetic material from its innate humanity and where all genetic material is treated just like any other chemical. The PTO has reiterated that patents do not confer ownership but rather exclusionary rights and genes subjected to being patented, in any event, have been separated from any connection to the human subject through scientific processes.¹²³ This legal power ignores dignitary concerns despite the fact that the individual himself does not experience the scientific "cleansing" process. The dignitary concerns of an individual or societal group are irrelevant when "[a]n individual subject is denied any claims or connection to her genetic material once it enters a lab where the legal-scientific process of purification and isolation eclipses all previous genetic ties."¹²⁴

Although this supposition is relevant for challenges to initial patenting, it

genes, as the human person should not be subordinated to other values).

118. *See id.* at 424.

119. *See id.*; *see also* Sturges, *supra* note 1, at 244-45 (arguing that less developed countries are especially wary of the ability to patent human genetic material, believing that such patenting "reduces human life to a commodity and amounts to tampering with nature").

120. *See* Public Comments on the United States Patent and Trademark Office: Revised Interim Utility Examination Guidelines, Comment 39, 65 Fed. Reg. 3425 (Jan. 21, 2000), available at <http://www.uspto.gov/web/offices/com/sol/comments/utilguide/ipcb.pdf>.

121. *See* Sturges, *supra* note 1, at 244-45.

122. Kahn, *supra* note 1, at 423 (quoting Igor Kopytoff, *The Cultural Biography of Things: Commoditization as Process in THE SOCIAL LIFE OF THINGS: COMMODITIES IN CULTURAL PERSPECTIVES* 64, 84 (Arjun Appadurai ed., 1986)).

123. *Id.* at 425-27.

124. *Id.* at 434-44.

is arguable that such dignitary concerns could be vindicated in a substantive claim of unjust enrichment. In such a case, the stripping or cleansing process itself, which results in genetic material capable of patenting, would not be at issue. It is not the exclusivity or ownership *per se* which is in dispute, but rather the inequity that results. Where unjust enrichment filled gaps in the tort laws cited in *Greenberg*, it is potentially available to remedy the harms created, but not addressed by intellectual property law, where the appropriation of one's genetic identity violates cultural, spiritual, or religious mores and freedoms.

B. The Effects of Patenting Human Genetic Material on Health Care

Numerous and diverse arguments suggest that the patenting of human genetic material impedes medical research and is a potential threat to human health.¹²⁵ These assertions could also provide a basis upon which courts could sustain claims of unjust enrichment, whether brought by societal groups challenging the practice as detrimental to public health or by individual plaintiffs where specific medical harms are at issue.

Some critics focus on the basic detriment resulting from the acquisition of the patent, while others assert that at certain points in the scientific process the patent becomes more detrimental. Francis Collins, director of the Human Genome Project, expressed concern that "putting toll booths on basic science" will stifle the progress that these patents are meant to encourage.¹²⁶ Frequent commentators Michael A. Heller and Rebecca Eisenberg warn that "[a] proliferation of intellectual property rights upstream may be stifling life-sustaining innovations further downstream in the course of research and product development."¹²⁷ These arguments thus share the fundamental premise that broad patents have negative consequences.

Professor Lori B. Andrews has discussed the ramifications of genetic patenting and categorized the harms produced.¹²⁸ These include the impediments to research, problems in verification resulting from the exclusivity of the patent-holder, the resultant deterrence to innovation based on the patenting of gene fragments and multiple holders of rights, and the problems created by excess rights being granted to the original holder of a patent.¹²⁹ Other harms include the actual damage to health care created by

125. See, e.g., Andrews, *supra* note 2, at 79-81.

126. See Hill, *supra* note 2, at 241 (citing Ken Garber, *Homestead 2000: The Genome, SIGNALS*, Mar. 3, 2000, available at <http://www.signalsmagazine.com/signalsmag.nsf/0FD168FB6C42ACF6E882568950015E2D0>).

127. See Heller & Eisenberg, *supra* note 2, at 698.

128. See Andrews, *supra* note 2, at 79-96.

129. *Id.* at 80-96.

patents, such as restricted access to testing, the potentially inadequate quality of testing, the potential upset in the traditional physician-patient relationship, and the drain on resources in the area of training.¹³⁰ An examination of the implications of human gene patenting illuminates the potential for a variety of plaintiffs to apply the broad concepts of equity in claims of unjust enrichment against potential defendant patent holders.

Because of human genetic patenting, scientists and researchers become reluctant to share materials, data, and information as profit motives create a basic impediment to research.¹³¹ For example, research for diseases such as autism is hindered if tissue samples are not shared.¹³² As a result of the commercialization of research, publication of information likewise is delayed or withheld.¹³³ Cooperation between scientists is diminished because of intentional withholding of data,¹³⁴ while the troubling prospect of the impossibility of duplicating published research arises.¹³⁵

Research may further be impeded where, because of patents, results are not subject to verification.¹³⁶ A patent holder may exclude others from evaluating and duplicating his research and can require licensing for further study of a genetic indicator of a disease, such as a mutation, within a population. Thus, claims of the original patent holder as to the prevalence of such an indicator cannot be verified.¹³⁷ A rush to profit from the genetic testing that ensues oftentimes occurs without enough data to confirm the accuracy of the predictability of such testing.¹³⁸ This restriction on verification can also create problems in the realm of forensic DNA testing.¹³⁹

The existence of patents on small fragments of genes, known as Express Sequence Tags, creates multiple rights-holders and high transaction costs, further impeding innovation.¹⁴⁰ Various biotechnological firms such as Incyte and Hyseq are patenting and have applied for millions of patents on

130. *Id.*

131. *Id.* at 80-81.

132. *Id.* (discussing Eliot Marshall, *Whose DNA is it Anyway?* 278 SCI. 564, 564 (1997)).

133. Andrews, *supra* note 2, at 80-81 (discussing Mertz et al., *Diagnostic Testing Fails the Test*, 415 NATURE 577, 577-79 (2002)).

134. *Id.*

135. *Id.* at 82 (discussing Blumenthal et al., *Data Withholding in Academic Genetics*, 473 JAMA 473, 477 (2002)).

136. *Id.* at 81.

137. *Id.* at 81-82.

138. *Id.*

139. Andrews, *supra* note 2, at 82.

140. *Id.* at 83 (citing Donald L. Zuhn, Jr., *DNA Patentability: Shutting the Door to the Utility Requirement*, 34 J. MARSHALL L. REV. 973, 981 (2001)).

these segments, where a partial segment of a gene could potentially be useful.¹⁴¹ Richard Gibbs, the director of the Human Genome Sequencing Center, analogizes this phenomenon to a land-grabbing: “Most of us are enthusiastic about oil drillers or gold miners who work their own patch and discover riches, but less enthusiastic about the vast amounts of territory being claimed without any real knowledge about what’s in it.”¹⁴²

Thus, a researcher exploring a cure for breast cancer would have to negotiate “with not only the patent holder for the full BRCA1 and BRCA2 genes, but with all of the other holders of patents who had discovered and patented any of the hundreds of other mutations in that gene.”¹⁴³ Similarly, the ability to create a gene therapy could be based upon a grant of permission or the formation of contracts with numerous patent holders. A refusal to negotiate by any one of these holders or a denial of access to databases based on restrictive costs creates an inefficient market, where both the patent holders and potential consumers of such therapy would be harmed.¹⁴⁴

Oftentimes too many rights are granted to the holder of an original patent on a gene.¹⁴⁵ The original owner can thus restrict its use or require costly licensing fees from a subsequent researcher. This is particularly problematic where small gene fragments, whose functions are unknown, are patented, such as in the case of AIDS research.¹⁴⁶

A company applied for a patent on a genetic sequence related to a receptor, while at the same time AIDS researchers worked on a receptor gene CCR5, which in humans produces a protein used by the HIV virus to infect its victims.¹⁴⁷ The original patent was granted to the company for the receptor HDGNR10 and “all possible embodiments associated with the receptor.”¹⁴⁸ This receptor turned out to be the same as receptor CCR5 and the original applicant, unaware of the implication for AIDS research,

141. *Id.* at 84 (citing Garber, *supra* note 126).

142. See The NewsHour with Jim Lehrer (PBS television broadcast Mar. 1, 2000) (transcript available at http://www.pbs.org/newshour/bb/health/jan-june00/genome_sharing_3-16.html (last visited Apr. 7, 2006)).

143. Andrews, *supra* note 2, at 85.

144. *Id.*

145. *Id.* (citing CARL SHAPIRO, NAVIGATING THE PATENT THICKET: CROSS LICENSES, PATENT POOLS AND STANDARD-SETTING, INNOVATION POLICY AND THE ECONOMY 121 (Mar. 2001), available at <http://www.haas.berkeley.edu./shapiro/thicket.pdf>).

146. *Id.* at 87.

147. *Id.* (citing Nathan Seppa, *Anti-HIV Mutation Poses Hepatitis Risk*, SCI. NEWS, Feb. 24, 2001, at 127 (discussing how a mutated CCR5 creates a defective receptor protein so that HIV is unable to enter and attack the cell)).

148. *Id.* at 87 (citing Pat Carson & Melissa Mandrgoc, *Gene-Based Drugs Challenge Patent Process; Statutory Requirements May Help to Address Concerns Over Applications Filed on DNA Sequences*, 226 N.Y.L.J. 73 (2001)).

retained exclusive rights.¹⁴⁹ Thus, the company could license and charge others for therapies or tests utilizing the CCR5 gene. One such party was the National Institutes of Health, which had previously been studying the gene, but was now excluded from research.¹⁵⁰ In these instances, patents awarded early in the scientific process, or “upstream” patents, create disincentives to further discovery of potential health benefits.¹⁵¹

The patent regime also impacts access to and the quality of testing for genetic disease, where patent holders frequently grant either exclusive licensing rights to their own laboratories or grant licenses to a limited number of other laboratories. This occurred in the *Greenberg* case, where the plaintiffs alleged that such practices limited accessible and affordable tests for Canavan disease.¹⁵² The discovery of various mutations in the same gene causing a specific disease is also limited by this exclusionary testing, where the mutations are difficult to find. One recent example involves breast cancer screening. A European patent related to the BRCA1 breast cancer gene was granted to a U.S. company, Myriad Genetics, “which covered all methods for diagnosing breast cancer by comparing a patient’s gene to the gene sequence described in the patent.”¹⁵³ The company then insisted that all such tests for breast cancer should be sent to its own laboratory, despite the fact Myriad’s test only assessed ten to twenty percent of the potential mutations that could be found in the gene.¹⁵⁴ This move precluded the possibility that certain other mutations causing the disease would be found, which was confirmed when a French physician found a mutation in an American family missed by the Myriad test.¹⁵⁵

This granting of broad patent rights further hampers efforts in the field of pharmaceutical research based on genetic research, where “[p]harmaceutical companies can now exercise property ownership over both the drug to treat a disease and the microorganism that causes it.”¹⁵⁶ This exclusionary right to genetic material may also hamper research

149. Andrews, *supra* note 2, at 87.

150. *Id.* at 88.

151. *Id.*; see also Heller & Eisenberg, *supra* note 2, at 698.

152. Greenberg v. Miami Children’s Hosp. Research Inst., Inc., 264 F. Supp. 2d 1064, 1067 (S.D. Fla. 2003).

153. Andrews, *supra* note 2, at 89.

154. *Id.* at 89-90 (discussing Steve Benowitz, *French Challenge to BRCA1 Patent Underlies European Discontent*, 94 J. NAT’L. CANCER INST. 80, 80 (2002)).

155. *Id.* at 90 (citing Sophie Gad et al., *Identification of a Large Rearrangement of the BRCA1 Gene Using Colour Bar Code on Combed DNA in an American Breast/Ovarian Cancer Family Previously Studied by Direct Sequencing*, 38 J. MED. GENETICS 388 (2001) (stating that no “BRAC1 or BRCA2 gene mutation was identified by direct DNA sequencing” on an individual who had a high probability of carrying the genetic mutation)).

156. *Id.* at 90 (citing Krinsky, *supra* note 2, at 37).

dealing with the development and discovery of new drugs. A pharmaceutical company might apply for a patent on a certain test in order to determine the effectiveness of a particular drug. Then, it might neither develop the test nor let anyone else develop it, as the use of the test could limit the potential customers for the drug itself.¹⁵⁷ Not only does this imperil the health of potential users of pharmaceuticals, the process of privatization also results in “the escalating price of pharmaceuticals and therapeutic tests.”¹⁵⁸

In addition to these potential concerns, it is arguable that the very nature of the patient-physician relationship is threatened by the practice of patenting human genetic material.¹⁵⁹ Where the physician is also involved in research pursuits with financial incentives involved, the trust of his patient is vulnerable. In *Moore v. Regents of the University of California*, such concerns were alleviated by the requirement that informed consent also include a physician’s duty to disclose such financial intent, including the intent to patent a particular cell or gene.¹⁶⁰ In *Greenberg*, the premise was narrowly drawn, excluding physicians whose concerns related to research, not therapy.¹⁶¹ Thus, with no duty to disclose such intentions, “due to the enticing possibility of vast profits, many researchers are not sharing tissue samples or preliminary findings” in the race to discover a gene which might prove profitable.¹⁶² Patients then depend upon physician-researchers for cures to their illnesses and thus have reason for mistrust. The desire to volunteer, to contribute to such research, is diminished by the profit motives of those involved in such endeavors.

Finally, another concern involves the general consumption of resources. Where the effective training of future physicians, laboratory personnel, and scientists may be compromised by limitations on genetic testing, legal battles involving patent infringement claims could lead to costly suits and vast settlements.¹⁶³

157. *Id.* at 91 (citing Krinsky, *supra* note 2, at 37).

158. Krinsky, *supra* note 2, at 37.

159. Andrews, *supra* note 2, at 92-94 (discussing the implications of patenting human genetic material and considering the cases *Moore v. Regents of the Univ. of Cal.*, 249 Cal. Rptr. 494, 502 (Cal. Ct. App. 1988) and *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479 (Cal. 1990)).

160. *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479 (Cal. 1990).

161. *See Greenberg v. Miami Children’s Hosp. Research Inst., Inc.*, 264 F.Supp.2d 1064, 1069 (S.D. Fla. 2003).

162. Andrews, *supra* note 2, at 94.

163. *Id.* at 95 (discussing a patent-infringement case with a \$200 million dollar settlement).

VI. POTENTIAL APPLICATIONS OF UNJUST ENRICHMENT

The pool of potential plaintiffs and defendants in cases dealing with the practice of patenting human genetic material is extensive considering the effect upon human dignity and private and public health care. Whether cases of unjust enrichment are brought by large societal groups or classes or individual plaintiffs, the elements of the prima facie case can be proven where notions of 'benefit' are broad and adherence to traditional and flexible notions of equity determine whether the retention of the benefit is unjust. Although not limitless, because defenses will arise and proof will be determined by the nature of the cases, examples of potential claims illustrate the far-reaching possibilities of the unjust enrichment claim to deter the practice of patenting human genetic material.

A. Potential Claims of Societal Groups

1. Claims based upon dignitary concerns

Where ethical, cultural, political, religious, or spiritual concerns conflict with the concept of patenting human genetic material, it is possible that certain populations might prevail in litigation. Defendant biotechnology companies that appropriate genetic material from patients or research subjects without their consent or knowledge and then patent and profit from their use could be liable. Suits of this nature would conform to the definitional requirements of the Restatement of Restitution, where "a person who has been unjustly enriched at the expense of another is required to make restitution to another."¹⁶⁴ An unauthorized use of genetic material represents a detriment, including a loss of dignity, religious freedom, and the essence of one's own humanity. According to the doctrine, these losses do not have to be quantified, nor must they be derived from any particular wrongful transfer. Traditional, broad-based notions of equity could determine whether the retention of these benefits is unjust.

Certainly, considerations of justice could provide the rationale for a finding of inequity. The absence of consent to the patenting and profiting of genetic material may be all that is needed to prove that the retention of the benefit is unjust in potential suits invoking dignitary losses. In *Edwards v. Lee's Administrator*, use of a portion of a cave was without the consent of the owner and the plaintiff's losses were unidentifiable.¹⁶⁵ In the *Cyanamid* case the court stated, "[c]learly there is no requirement, then, that

164. See RESTATEMENT FIRST, *supra* note 9, §1 cmt. a.

165. See *Edwards v. Lee's Admin.*, 96 S.W.2d 1028, 1033 (Ky. Ct. App. 1936).

all patentable ideas actually be patented.”¹⁶⁶ The court held that “a defendant who uses a benefit provided by the plaintiff in an unauthorized and unfair manner may be liable in Colorado for unjust enrichment.”¹⁶⁷

Where indigenous populations represent potential plaintiffs for unjust enrichment claims against biotechnology firms, basic moral precepts could provide a rationale for the finding of an inequity. Just as Native Americans were dispossessed of their lands, “bioprospecting” and patenting genes from isolated, indigenous populations strips those populations of their dignity and their genetic identity. As such “[s]ome indigenous groups have become suspicious of cell line prospecting and consider it a form of Western thievery of third world resources.”¹⁶⁸ In response, one international group has been organized to respond to the question of whether there is a right to profit from someone else’s cell line.¹⁶⁹ Another group’s ethical guidelines propose “the sharing of financial rewards it might receive from cell lines with the communities from whom the cell lines were obtained.”¹⁷⁰ Thus, considerations of equity and morality exist in the profiting on the unauthorized use of human biological material. The contemporary use of unjust enrichment could perhaps circumvent demands for massive reparations in the future.

Despite the fact that courts have established that “obtaining a patent does not preclude the defendants from being unjustly enriched,”¹⁷¹ the use of the claim in these cases regarding dignitary, spiritual, or religious concerns would unquestionably be considered novel. The potential defense that any donation of such material might be considered a ‘gift’ in the context of research (where informed consent is not extended and does not require the disclosure of the intent to patent and profit to such donors) might preclude its use. In turn, defendant companies could also argue that the retention of the benefit is neither unjust nor immoral, based upon showings of advancement in health care made available to such populations.

Nevertheless, it is exactly in such circumstances that the historically broad and flexible aspect of the claim has been used to establish an unidentifiable sense of moral righteousness and vindicate wrongdoing.

166. Univ. of Colo. Found. V. Am. Cyanamid Co., 153 F. Supp. 2d 1231, 1242 n.8 (D. Colo. 2001).

167. See *id* at 1243 (quoting *Cyanamid IV*, 105 F. Supp. 2d at 1175).

168. See Krinsky *supra* note 2, at 37.

169. *Id.* at 38 (discussing the Indigenous Peoples Coalition Against Biopiracy).

170. *Id.* (discussing a draft of the ethical guidelines for the Human Genome Diversity Project).

171. See *Greenberg v. Miami Children’s Hosp. Research Inst., Inc.*, 264 F.Supp.2d 1064, 1069 (S.D. Fla. 2003) (citing *Chou v. Univ. of Chicago*, 254 F.3d 1347, 1363 (Fed. Cir. 2001) for recognizing a claim for unjust enrichment in the context of gene patent dispute).

Exemplified by the cohabitation scenarios where the common law has provided no other grounds for relief, unjust enrichment exists to restore human dignity and right moral wrongs. Where a financial remedy might not vindicate these dignitary losses, its deterrent effect on the practice of patenting and profiting from human genetic material certainly denotes "restitution" and the claim of unjust enrichment should prevail.

2. Claims based upon the unfair and unauthorized use of human genetic material given by research subjects and/or providers of human genetic material

It is not only where dignitary losses have occurred, but also in areas dealing with medical research that the lack of consent to the patenting and profiting from human genetic material could provide the basis for a claim in unjust enrichment. The *Greenberg* case dealt with a lack of consent for patenting and profiting from human genetic material in a scenario that involved "more than a donor-donee relationship."¹⁷² Nonetheless, it is possible that a type of strict liability for defendant biotechnology firms or research institutions could arise where potential plaintiff subjects and donors are unaware of the financial implications of patented genes or of the potential harms created by the practice. Plaintiffs may establish an unauthorized use of their material whether it had been given for research purposes or simply had been stored in a defendant's institution. Additionally, whether or not such donor/plaintiffs are giving this material with an expectation of payment or compensation might only be relevant in cases asserting an action in quasi-contract and, in many cases, the requirement may not be part of a prima facie case.

3. Claims based upon impediments to research and harms to the public health

Where research has been impeded as a result of the patenting and profiting from the human genetic material, patients denied the potential benefits of medical research and breakthroughs in that disease could avail themselves of the unjust enrichment claim. Patent holders withholding information, data, and material stand as potential defendants, if privatization and profit motives hinder the efforts of those searching for a particular cure. Where a patent holder excludes others from evaluating and duplicating research, claims as to the prevalence of certain genetic indicators cannot be verified and unnecessary testing for a certain disease can occur, then creating a class of plaintiffs undergoing such tests.

172. *Id.*

The “land grab” of broad patents resulting in the problems of multiple rights-holders could similarly produce claims where the ability to create new products and therapies has been delayed. The harms created by overly broad patents granted to the original holders could also lead to potential suits. For example, potential AIDS patients may claim that the owners of the original patent on the receptor gene were unjustly enriched by excluding the NIH in continuing to research the potential causes and cures of the disease. The health concerns created by the exclusionary practices involved in patents, such as the inability to detect a mutation for breast cancer, could lead to suits against the patent holder, not only in tort, but also in the substantive use of the unjust enrichment claim. Pharmaceutical company patent holders who do not develop certain tests on drugs, where the test could limit the potential customers for the drug itself, both imperil the public health as well as escalate the price of drugs and testing and might also be subject to claims of unjust enrichment.

These harms may pave the way for suits by large classes of plaintiffs similar to the “dangerous product” cases and could proceed where the genetic material in question exists as a benefit. This could occur even where potential plaintiffs may not actually have been donors of biological and genetic materials or even where they might have consented to the use of their genetic material as the basis for a patent. Despite consent potentially having been given, the benefit could be categorized as the defendants’ externalities, where the avoidance of costs associated with patenting this genetic material would be considered a resultant benefit. The potential limitations to this notion of benefit are analogous to dangerous product cases. These biotechnological companies and research institutions potentially have no duty to abate the costs associated with patenting human genetic material and any medical harms created by the practice could be considered too attenuated for liability to attach. Nevertheless, the precedential value of dangerous product cases establishes the concept of benefit in the area of human gene patenting and future class action suits.

Similarly, the concept that the conferral of a benefit can be established without an actual transfer having occurred, as reflected in the insider trading cases, could aid large classes of plaintiffs claiming that an unjust enrichment has occurred, even where *their* actual genetic material is not at issue. That a benefit can exist independent of an actual transfer could also assist plaintiffs where issues of identification arise when their genetic material has been stored in bio-banks.

Based upon the effects and impact of patenting human genetic material, it is arguable that profits resulting from gene patenting were to the detriment, or *at the expense*, of potential societal plaintiff groups. As in any unjust enrichment case however, whether the retention of the benefit “will

give offense to equity and good conscience” will be critical in the analysis of any potential claims.

The United States Constitution provides Congress the power “to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”¹⁷³ Thus, an economic incentive was introduced to promote growth and innovation. Despite this, it is apparent that the Human Genome Project’s involvement in the corporate world induced companies to focus on the ability to acquire immediate and immense profits as a result of patenting human genetic material.¹⁷⁴ This practice, which finds support in the law of intellectual property, has impeded, rather than advanced, the larger realm of scientific progress and discovery, the original goal of the Constitutional mandate. By acknowledging the harms created by the system of patenting, the belief that “the appropriation of knowledge as intellectual property . . . will yield a greater public good in the long run” is “a dubious assumption.”¹⁷⁵

Certainly, defenses to this assertion will be offered, suggesting that the patenting of human genetic material is not unjust and that the practice does not produce the harms claimed but rather fosters innovation, progress, and success in the fight against genetic disease. The varying factual scenarios will settle these disputes and courts will define the limits and boundaries on the perceived inequity. Nevertheless, the assertion that medical knowledge is not serving a common good, a fundamental value which is “being superseded by the normative changes taking place in biomedical science,”¹⁷⁶ provides an overriding rationale to support a claim that “the retention of the benefit is inequitable.”¹⁷⁷

This general rationale could be supported by two underlying justifications for a finding of an inequitable retention of a benefit. Potential biotechnological and pharmaceutical corporate defendants are making excessive profits when corporations overreach and overcharge the public, thus producing profits that can be considered a windfall for those parties. Both instances occur to the detriment of society, suggesting the claim that the retention of these profits/benefits is unjust. There is no doubt that the existence of human genetic material supplied to research institutions, biotechnological or pharmaceutical companies, is a benefit within the broad and encompassing definition of the term. Whether the profits attained as a

173. U.S. CONST. art I, § 8.

174. See e.g., Krimsky, *supra* note 2, at 39.

175. *Id.*

176. *Id.* at 35.

177. See e.g., *Greenberg*, 264 F. Supp. 2d at 1072.

result of the acquisition of this benefit are excessive remains an open, fact-specific question to be decided by courts in the future. The facts of *Greenberg* are illustrative of the type of evidence courts may encounter in claims that profits are excessive, stressing the quantitative nature of the concept.

In 1988, four years after the Canavan gene was discovered, Miami Children's Hospital sent out letters notifying clinics and researchers of the need for a license prior to testing for the gene.¹⁷⁸ The director of one lab located at the University of Pennsylvania Health System received three such letters.¹⁷⁹ The first indicated that although she could conduct a limited number of tests at a cost of \$12.50 each, the license could be revoked at any time.¹⁸⁰ The second letter stated that the lab could obtain samples but not perform testing and would have to send the samples to a licensed lab.¹⁸¹ The third letter charged \$12.50 for each test that had already been performed, which had numbered under 100, and demanded an end to testing.¹⁸² As an important contrast, no royalties are collected from researchers for using the gene for Tay-Sachs disease, although there is a patent on it.¹⁸³

Instances of overcharging and overreaching might also be considered in the context of human gene patents and drug companies where the privatization of genetic material results in "the escalating price of pharmaceuticals and therapeutic tests."¹⁸⁴ Where the price of prescription drugs is subject to political debate, the isolation of patents on human genetic material as an underlying cause of these prices might be determinative in a finding that biotechnological firms are overreaching and overcharging as a result of their exclusionary patents.

It is also arguable that the practice of acquiring broad patents resembles the innate concept of a windfall. The exclusivity created by a patent on a small gene-fragment extends to every possible use and exploitation of its potential. Unlike the discovery of new drugs, "the discovery of new genes does not require the same economic incentives."¹⁸⁵ The costs of performing research and development that come with animal research and clinical trials, as well as obtaining FDA approval, do not arise in the process of

178. Research USA, *Gene patent lawsuit may radically affect research*, June 30, 2003, <http://www.ResearchResearch.com>.

179. *Id.*

180. *Id.*

181. *Id.*

182. *Id.*

183. *Id.*

184. See Krinsky, *supra* note 2, at 37.

185. Andrews, *supra* note 2, at 77.

gene discovery.¹⁸⁶ Thus, the small costs in discovering the fragment resulting in huge profits down the line can perhaps be viewed as inequitable when considering the effects of the practice. It is indicative of the type of claim that could be brought in future cases by plaintiff classes where, despite the *legality* of the company's dealings, under tort, contract and property law, the retention of the benefit provided to the defendant could be considered unjust.

deCODE Genetics is a company which deals with population-based genetic information and whose primary asset is a sample bank and database of genealogical, genetic, and disease information on extended Icelandic families.¹⁸⁷ Research subjects are informed that they relinquish all claims to financial gains resulting from any studies in which they are involved.¹⁸⁸ In 2001, the company entered into an alliance with a corporation, Hoffman-La Roche, "to develop and market DNA-based diagnostics for major diseases."¹⁸⁹ This alliance "is potentially worth \$300 million to deCODE."¹⁹⁰ There are other deals involving collaborations on drug development where deCODE will be paid a milestone payment each time the corporation maps a gene in a common disease and Hoffman-La Roche discovers the drug.¹⁹¹ Thus, the providers of this genetic material could certainly assert that they had conferred a benefit, the retention of which is unjust, relying on rationales of excessive profits and windfalls.

Additionally, as in the ERISA cases, "societies' reasonable expectations of person and property"¹⁹² are implicated by the harms caused to the common good by the practice of patenting human genetic material. Federal legislation passed in the 1980s gave intellectual property rights in research findings to institutions that had received federal grants.¹⁹³ Thus, publicly-funded discoveries could be patented and licensed. "The basic research that yields discoveries of genetic associations with disease have been

186. *Id.*

187. See generally deCODE Website, <http://www.decode.com> (last visited Apr. 7, 2006).

188. deCODE Patient Consent Form, available at <http://www.decode.com/files/filemanager/website1/file148517.pdf> (last visited Apr. 7, 2006).

189. *deCODE and Roche Sign Landmark Alliance to Develop Integrated DNA-based Diagnostic Tools and Related Services and Software*, July 2, 2001, <http://www.decode.com/main/view.jsp?branch=167011&e342RecordID=481&e342DataStoreID=3917>.

190. *Id.*

191. Press Release, Roche Pharmaceuticals, Roche and deCode Genetics Identify Chromosomal Location of Genetic Risk For Osteoporosis (Nov. 14, 2000), available at <http://www.rocheusa.com/newsroom/current/2000/pr2000111402.html>.

192. See, e.g., *Heller v. Fortis Benefits Ins. Co.*, 145 F.3d 487, 495 (D.C. 1998).

193. 35 U.S.C. §§ 200-212 (1994).

underwritten by the public.”¹⁹⁴ Accordingly, “the public increasingly feels it is paying twice for research - once to fund the research and then to the biotech companies mining this taxpayer-funded research.”¹⁹⁵ Not unlike the mistaken overpayment of pension funds in the ERISA cases, it is arguable that the public money used to promote the public health should be safeguarded and that the profits made by the retention of these benefits is a cost “unfairly borne by other members of the plan.”¹⁹⁶

It is the nature of the claim of unjust enrichment itself, however, which could provide favorable outcomes to groups or classes of potential plaintiffs. Broad and flexible notions of equity could find this deprivation of the common good as “something identifiable, *a priori*, by the exercise of a moral judgment anterior to legal rules.”¹⁹⁷ Moral judgments underlying cases range from cohabitation situations to plaintiffs unable to retrieve mistakenly lost possessions. Certainly in a cause of action where there are “no strict rules” and “everything depends upon the circumstances of the case,”¹⁹⁸ the retention of benefits accrued by the practice of patenting human genetic material is unjust. The “circumstances will give offense to equity and good conscience” if the practice continues. The harms created will potentially be deterred by the use of the substantive claim of unjust enrichment by groups and classes of plaintiffs affected by patents on human genetic material.

B. Individual Claims

Where large societal groups or classes of plaintiffs assert claims of unjust enrichment, these claims will most certainly be considered novel and potentially difficult to prove. Causes of action arising out of dignitary concerns might be considered too ephemeral, while the alleged harms to society too attenuated. Where transfers have not occurred or where consent has been given, new theories describing the nature of a benefit as the avoidance of a defendant’s externalities might not resonate in jurisdictions where such theories have been discredited. Thus, individual claims of unjust enrichment based upon the effects of patenting human genetic material might prove to be an easier and more effective deterrent, where specific instances of an unjust retention of a benefit can be found.

194. Andrews, *supra* note 2, at 78 (quoting Jon Merz et al., *Disease Gene Patenting is a Bad Innovation*, 2 MOLECULAR DIAGNOSIS 299, 301 (1997)).

195. *Id.* at 78.

196. *Heller*, 142 F.3d at 495.

197. See RESTATEMENT THIRD, *supra* note 9, § 1.

198. *Ames v. Provident Life & Accident Ins. Co.*, 942 F. Supp. 551, 558 (S.D. Fla. 1994).

1. Individual claims arising from dignitary concerns

The unauthorized use of genetic material resulting in the commodification of personal identity could be challenged by individuals as well as groups who have given their genetic material without the requisite informed consent regarding economic interests. An example of such would be a person whose individual DNA had been patented in contravention of that person's religious beliefs. In 1992, the United Methodist Church's genetics task force, which included a minister/geneticist and director of the prenatal screening lab at Georgetown University, in addition to two molecular biologists,¹⁹⁹ addressed patent laws related to genetic engineering by stating, "exclusive ownership rights of genes as a means of making genetic technologies accessible raises serious theological concerns" and "the issue is not science versus religion, it's the commodification of life – the reduction of life to its commercial value and marketability."²⁰⁰ Similarly, the executive director of the Southern Baptist Convention's Christian Life Commission found that the process of patenting "represents the usurpation of the ownership rights of the Sovereign of the Universe." Likewise, Jewish leaders have expressed the notion that "the biotech industry can survive without the patenting process."²⁰¹

Thus, as a motion filed in the *Greenberg* case has expressed, "an individual who opposes a gene patent on religious grounds is not sufficiently protected if his gene can be patented without his knowledge or consent."²⁰² Although he has not been sufficiently protected as he would have been had informed consent been required, he could have still find recourse in a claim of unjust enrichment.

2. Individual claims based upon the unfair and unauthorized use of human genetic material given by research subjects and/or providers of human genetic materials

It is quite possible that an individual who has given his genetic material as a research subject without knowing or understanding the effects of future patents based upon this material might assert a claim that the defendant patent holder has been unjustly enriched by the unauthorized use of his genes. Although the 'ongoing collaboration' presented by the facts of

199. See Richard Stone, *Religious Leaders Oppose Patenting Genes and Animals*, SCIENCE, May 26, 1995, at 1126.

200. *Id.*

201. *Id.*

202. See Plaintiffs' Motion and Memorandum of Law for Reconsideration of Order Dismissing Count I of Plaintiffs' Complaint, *Greenberg v. Miami Children's Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064 (S.D. Fla. 2003) (No. 02-22244-CIV-MORENO).

Greenberg might prove distinctive, the analysis of benefit and an unjust retention of such a benefit may be applicable based upon the broad and flexible nature of the cause of action. When the inequity of the retention of the benefit is based on the various circumstances of each case, there is no necessity that any facts in such a claim must be identical to the *Greenberg* scenario.

Similarly, an individual who has not specifically been the subject or donor in the research context might also assert that his genetic material has been used in an unauthorized manner. Upon ascertaining that his existing or stored genetic material has been the basis of a patent and that profits were realized from such a patent, an individual who had been unaware of this occurrence might claim that the defendant patent holders were unjustly enriched. Not unlike the revenue-producing cave in the *Edwards* case, the use of such tissue or DNA taken in the course of standard medical procedures results in profits accrued by the defendant patent owner, a benefit received by the defendant, the retention of which is unjust.

3. Individual claims based upon specific medical harm

The possibility of substantive unjust enrichment claims based upon the effects of human gene patents on an individual's health and/or medical treatment is potentially great, where unlike claims of medical malpractice, causation is not an element requiring proof in a *prima facie* case. Thus, specific harm resulting from patenting and profiting from human genetic material could be proven to be the basis of claims against institutional or corporate patent holders without the difficulty of proving that the exclusive patents on a gene *caused* the specific medical harm. Rather, the basis in liability would exist in the inequitable retention of the benefits provided by the exclusionary practices causing the harms.

These harms may arise either from lack of access to and the poor quality of tests for genetic disease. Should a patient desire a test for the gene associated with Alzheimer's disease, for example, the company holding the patent on the specific gene might allow the test only to be done at its laboratory, which might be prohibitive for that hypothetical patient.²⁰³ Thus, a delayed diagnosis resulting in medical harms will subject a defendant patent holder to potential liability.

The practice of charging restrictive licensing and royalty fees for the use

203. See Andrews, *supra* note 2, at 89 (discussing Julian Borger, *Rush to Patent Genes Stalls Cures for Disease*, GUARDIAN, Dec. 5, 1999, at 1); see also Andrea Knox, *The Great Gene Grab: Firms Toss Researchers For a Loop*, PHILADELPHIA INQUIRER, Feb. 13, 2000, at A1 (discussing how Athena Diagnostics of Worcester, Massachusetts, charges twice as much as a hospital would for Alzheimer's gene testing).

of tests developed from patented genes also can lead to cases where access to testing is denied. For example, the Canadian province of British Columbia discontinued testing for breast cancer because their system could not afford the costs of the tests as charged by the Myriad Company.²⁰⁴ Similarly, an individual plaintiff involved in a case such as *Greenberg* could claim that he was either denied access to a genetic test or could not afford one due to the effects of exclusive gene patenting. This could occur *even where he had provided the genetic material used as the basis for identifying the gene sequence causing the disease.*

Additionally, harm might result when a patent holder excludes others from testing for their exclusively owned genes, eliminating the possibility that various unknown mutations in the same gene will be found. This situation was suggested by the actual Myriad breast cancer case.²⁰⁵ A patient with a genetic mutation causing breast cancer which was missed as a result of exclusionary testing could potentially assert that the patent holder company had been unjustly enriched as a result of such practices.

Claiming that an illness and its ensuing treatment costs resulted from an undiagnosed or misdiagnosed genetic test might be difficult to prove in a medical malpractice case, where standards of care and causation create limits on liability. However, an individual patient suffering from the inability to have treated a potentially treatable disease due to inaccessible, unaffordable, or inadequate testing might assert that a defendant patent holder has been unjustly enriched. The acquisition of genetic material is arguably a benefit, acknowledged in the attempt to procure the patent itself. An individual patient's suffering could by itself establish that the retention of the benefit is inequitable and unjust when caused by the practice of patenting human genetic material. The underlying rationale is a simple, basic moral principle.

Additional rationales such as windfalls, excessive profits, and public policy concerns might exist for an individual as well as a societal group or class as the basis for a claim in unjust enrichment. The defendant patent holders' profits could be illuminated in the context of myriad cases illustrating the effects of patenting human genetic material on human health. These include scenarios such as an older patient struggling with and unprepared for the ravages of Alzheimer's disease, a family torn apart by a young mother's death caused by ignorance of genetic markers predicting breast cancer, or a young child dying from Canavan's disease. These

204. Andrews, *supra* note 2, at 91 n.166 (hospitals in British Columbia had a hereditary cancer program budget of \$500,000, while the cost of Myriad testing alone was close to \$1.5 million).

205. *Id.* at 89-90 (discussing Steven Benowitz, *French challenge to BRCA1 Patent Underlies European Discontent*, 94 J. NAT'L CANCER INST. 80, 80 (2002)).

claims based upon the lack of a specific genetic test will again potentially be considered novel. However, in the face of these and numerous other potentially troubling occurrences, the historic and traditional nature of the cause of action could be determinative where “fundamental principles of justice, equity, and good conscience”²⁰⁶ have been violated.

VII. CONCLUSION

A fundamental irony exists in the *Greenberg* decision in the court’s concern that upholding the informed consent claim would somehow impede medical research. The court agreed with the defendants’ contentions that “this requirement would have pernicious effects over medical research, as it would give complete control over how medical research is used and who benefits from that research.”²⁰⁷ Ultimately, the opinion looks at the practical implications, stating, “it would be unworkable and would chill medical research as it would mandate that researchers constantly evaluate whether a discloseable event has occurred. Second, this extra duty would give rise to a type of dead hand control that research subjects could hold because they would be able to dictate how medical research progresses.”²⁰⁸

These expressions can potentially be seen as the court misunderstanding, denying, or ignoring the extensive and numerous problems resulting from the practice of patenting human genetic material. Perhaps it can even be viewed more cynically as a veiled protection of the economic interests of the biotechnological industry. It is interesting to note that the court dismissed the fact that the American Medical Association (“AMA”) did not seem to share the court’s concern over chilling effects.²⁰⁹ Its guidelines state that “potential commercial applications must be disclosed to the patient before a profit is realized on products developed from biological material” and “human tissue and its products may not be used for commercial purposes without the informed consent of the patient who provided the original cellular material.”²¹⁰ Nonetheless, the court found that these ethical rules were not conclusively binding on the parties because they had been adopted after the plaintiffs had given their tissue to the defendants.²¹¹

206. *Greenberg v. Miami Children’s Hosp. Research Inst.*, 264 F.Supp.2d 1064, 1072 (S.D. Fla. 2003).

207. *Id.* at 1070.

208. *Id.* at 1070-71.

209. *Id.* at 1070 (citing AMA Code of Medical Ethics, E-208 Commercial Use of Human Tissue, available at <http://www.ama-assn.org/ama/pub/category/8427.html> (last visited Apr. 7, 2006)).

210. *Id.*

211. *Id.* at 1070.

However, it is possible that the dismissal of this other claim, coupled with the refusal to dismiss the claim of unjust enrichment, will have far greater implications for the developing law regarding the practice and effects of patenting human genetic material. Closing the door on informed consent of economic interests, yet acknowledging an inequity existed under the circumstances, predicts that litigation questioning the practice of patenting human genetic material will continue to proceed. In dismissing the conversion claim based upon the precedent in *Moore* that "one has no property interest in their body tissue and genetic information,"²¹² perhaps the court was attempting to prevent radical outcomes resulting from any fundamental change in property law. However, the duty to disclose economic interests illustrated by the AMA's guidelines seemingly offers a much narrower restriction on current practices. Informed consent requirements regarding human research offer choice, including economic choice, yet medical research involving human subjects continues. The use of the claim of unjust enrichment, however, questioning the practice of patenting and profiting from human genetic material has a much wider scope with broad and far-reaching implications.

The use of the cause of action will enable one to claim that a defendant has been unjustly enriched, requiring restitution to the plaintiff. A result exemplified by numerous situations, including the defendant's nondisclosure of economic interests; the loss of a plaintiff's dignitary interests such as religious belief or human identity; and where medical research and scientific progress has been impeded, causing either individual or societal harm. Historically broad and flexible notions of equity will identify these circumstances as giving rise to considerations of fairness and conscience, potentially implying and impelling a fundamental reordering of the system.

Numerous critics are already demanding a reconsideration of the practice of patenting and profiting from the use of human genetic material and various alternatives and policy options are being considered to address the inherent problems created by both research and biotechnological institutions.²¹³ The substantive claim of unjust enrichment and the underlying notion of restitution, filling the gap in property, intellectual property, and tort law, per *Greenberg*, is one such alternative to be considered in the ongoing debate.

212. *Greenburg*, 264 F. Supp. 2d. at 1074 (citing *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 487 (Cal. 1990), which noted that there have been no reported court decisions imposing conversion liability for the use of human cells in medical research).

213. See, e.g., *Andrews*, *supra* note 2, at 95-106 (describing various alternatives to human gene patenting).