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At Least Give the Natives Glass Beads:
An Examination of the Bargain Made between Iceland and
deCODE Genetics with Implications for Global Bioprospecting

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I. Introduction

1. Known best for fells and fjords,¹ glaciers and volcanoes,² Vikings³ and Björk,⁴ the tiny country of Iceland remained more of a travel curiosity than a subject of legal discourse until the beginning of 1999. The international radar of the bar blipped, however, when the Icelandic parliament granted to a private company a virtually exclusive license to the health records of the entire Icelandic people.⁵ In January 2000, the government finalized an agreement with deCODE genetics to build a national database from the health records with an eye toward understanding the genetic cause of disease and developing possible treatments.⁶
2. Iceland's bargain with deCODE not only capitalizes upon 85 years of data collection through the country's socialized medicine system,⁷ but also diversifies a "cod economy"⁸ and presses into service the national obsession with genealogy⁹ to aid in the hunt for faulty genes. A population of about 285,000 people,¹⁰ where "life is still fish,"¹¹ Iceland surprisingly is now home to the "mother of all genetic databases."¹²
3. The intellectual debate of lawyers, academics, scientists, and the average citizen has centered upon concerns over patient rights and confidentiality for the Icelandic database,¹³ but other lessons can be learned. Now that deCODE has begun to mature as a

¹ For an early travel guide filled with impressions of Iceland, *see generally* E.J. OSWALD, BY FELL AND FJORD OR SCENES AND STUDIES IN ICELAND (1882).

² DISCOVERY CHANNEL, INSIGHT GUIDE ICELAND 17-22 (Jane Simmonds et al. eds., 2001). Iceland's glaciers often sit on top of volcanoes, some of which are still active. An eruption may then produce mass flooding, in addition to the typical ash and lava products. *Id.* at 19.

³ *Id.* at 27; GUNNAR KARLSSON, ICELAND'S 1100 YEARS: THE HISTORY OF A MARGINAL SOCIETY 10-11 (2000). Colonization by Irish monks actually preceded the arrival of the Norsemen during the Viking Age. *Id.* at 9-10.

⁴ DISCOVERY CHANNEL, *supra* note 2, at 71-72.

⁵ Martin Enserink, *Iceland OKs Private Health Databank*, 283 SCIENCE 13 (1999).

⁶ MINISTRY FOR HEALTH & SOC. SEC., ICELAND, OPERATING LICENSE ISSUED TO ÍSLENSK ERFÐAGREINING EHF. STATE REG. NO. 691295-3549 LYNGHÁLS 1 REYKJAVÍK FOR THE CREATION AND OPERATION OF A HEALTH SECTOR DATABASE 3 (Jan. 2000), [http://government.is/interpro/htr/htr.nsf/Files/oplic/\\$file/oplic.pdf](http://government.is/interpro/htr/htr.nsf/Files/oplic/$file/oplic.pdf) [hereinafter OPERATING LICENSE]. *See also* deCODE genetics, Inc., *Company Milestones*, at <http://www.decode.com/company/history> (last visited Apr. 4, 2002) [hereinafter deCODE, *Company Milestones*]; Martin Enserink, *Start-up Claims Piece of Iceland's Gene Pie*, 287 SCIENCE 951 (2000).

⁷ *See* Robert Kunzig, *Isolated Icelanders Could be Key to Curing Disease*, SAN DIEGO UNION-TRIB., Jan. 6, 1999, at E5.

⁸ Thomas Borchert, *Iceland's "Cod" Economy Pins its Hopes on Gene Data*, DEUTSCHE PRESSE-AGENTUR, Sept. 14, 2001.

⁹ DISCOVERY CHANNEL, *supra* note 2, at 27.

¹⁰ STATISTICS ICELAND, ICELAND IN FIGURES 2000-2001, VOL. 7, at 4 (Björgvin Sigurðsson ed., 2002) (last known population value was 282,849 in December 2000). Currently, the estimated population of Iceland is 286,275. Statistics Iceland, *Key Figures*, at <http://www.statice.is/news/iceland.htm> (last visited Apr. 4, 2002). Statistics Iceland, a government ministry regulated by statute, publishes population data for the country.

¹¹ KARLSSON, *supra* note 3, at 357-60; *see also* OECD PUBL'NS & INFO. CENTRE, OECD ECONOMIC SURVEYS— ICELAND 101 (2001) [hereinafter OECD ECONOMIC SURVEYS— ICELAND].

¹² Thomas Grose, *The New Icelandic Saga: A Start-up Icelandic Biotech Firm is Finding Novel Ways to Exploit Its Unique Genetic Inheritance*, TIME, Sept. 29, 1997, at 42.

¹³ *See, e.g.*, R.C. Lewontin, *People Are Not Commodities*, N.Y. TIMES, Jan. 23, 1999, at A19 (chastising the implied consent aspect of the database, which requires Icelanders to affirmatively opt-out to be excluded); Hrobjartur Jonatansson, *Iceland's Health Sector Database: A Significant Head Start in the Search for the Biological Grail or*

corporation, we can examine whether Iceland struck the right balance between encouragement of the biotechnology industry and protection of the genetic history of its people. We may also ask what methods of controlling exploitation may be adopted by communities under study and what such targets can legitimately demand in light of deCODE's experience in Iceland. In other words, if there is "gold in them thar genes,"¹⁴ what deal should we reach with the miners?

4. This case study evaluates the scheme set up by the Icelandic government and provides an updated report on deCODE. After a basic introduction into the scientific principles which underlie deCODE's business plan, Section II outlines the license terms between the Icelandic government and deCODE, focusing on both the monetary and intangible costs and benefits for each party. Section III then rigorously examines deCODE from its current political, scientific, and market position. The section also analyzes the benefits accruing to Iceland from its association with deCODE. Section III thus presents a picture of deCODE in 2002—a healthy, active corporate body with an amazing asset bestowed by the Icelandic government—and attempts to evaluate what deCODE and Iceland have gained from the company's growth.
5. Section IV of this paper derives a set of observations, or lessons, that can be extrapolated from the Icelandic experience. The section begins by surveying the expansion of bioprospecting companies¹⁵ and the concurrent rise in regulatory activism. Section IV then outlines three considerations for future bioprospecting agreements that derive from the multifaceted evaluation of deCODE and Iceland presented in earlier sections. Though not applicable to every bioprospecting arrangement, the lessons presented in Section IV form a starting point for analyses that may substantially benefit both a target population and its prospective bioprospectors.

II. deCODE genetics: Homogeneity, Genealogy, and the Grace of the Icelandic Government

6. Headquartered in Reykjavík, Iceland, deCODE genetics currently employs approximately 600 scientists and support staff in the search for genetic mutations that cause dozens of common diseases such as osteoarthritis, schizophrenia, obesity, and many others.¹⁶ Kari

an Irreversible Error?, 26 AM. J.L. & MED 31, 42-56 (2000) (arguing that the terms of the license sufficiently protect privacy and violate no legal authority).

¹⁴ The phrase is borrowed from an Australian article about Celera and the human genome project, but most likely the analogy with gold mining had earlier origins. See Julie Lewis, *Gold in Them Thar Genes*, THE WEEKEND AUSTRALIAN, Mar. 25, 2000, at 21; Ian Gordon, *Genetics as it is Spoken: The Link Between Genes and Language*, NEW SCIENTIST, Sept. 7, 1991, at 60.

¹⁵ See, e.g., Jeff Hawkes, *Plain Genes; Quiet Culture a Perfect Fit for Scientists; Plain Lifestyle, Lineage and Willingness Make Research Click*, INTELLIGENCER J. (Lancaster, PA), Feb. 7, 2001, at A8 (reporting that the Amish are now a target of genetic study); *Italian start-up to begin gene research project in Sardinia*, GENOMIKA, Nov. 21, 2001, at 2; *IT insiders predict better times in 2002*, HERALD SUN, Jan. 12, 2002, at 50 (reporting on the collection of blood samples from European Jews in Israel).

¹⁶ Kim Frick, *deCODE CEO Stefansson Finds Genes in Iceland's Family Trees*, BLOOMBERG NEWS, Dec. 20, 2001 at LEXIS, News Library, News Group File, All. According to recent statements by Stefansson, the company is tracing the genetic font of sixty diseases. See *POPULATION, INC., Company Business & Marketing*, TECH. REV. (Cambridge, MA), Apr. 1, 2001, at 52 [hereinafter *POPULATION, INC.*].

Stefansson, a native Icelander and former Harvard Medical Center neuropathologist, conceived of the idea for the company in 1996 with fellow physician Jeffrey Gulcher.¹⁷ Incorporation in Delaware followed,¹⁸ with Stefansson leaving his tenure at Harvard to run the nascent corporation.¹⁹

7. This section explores the corporate strategy of deCODE and the company's relationship with the Icelandic government. By capitalizing upon (1) the homogeneity of the Icelandic population, (2) its people's penchant for genealogy,²⁰ and (3) deCODE's newly gained access to all of Iceland's medical records,²¹ the company aims not only to isolate the causes of disease, but also to enable drug discovery and pharmaceutical invention.

A. Homogeneity of Icelanders

1. Needle in a Haystack: Population Genomics in a Heterogeneous Society²²

8. Companies like deCODE rely on the scientific theory known as population genomics for their ultimate success or failure.²³ According to genomic theory, scientists can discover gene mutations that cause disease by carefully comparing the DNA of a healthy person with the DNA of a person suffering from a certain disease:

Genomics, the search for disease-causing genes, is rapidly becoming an indispensable tool in the pharmaceutical industry.... The principle of genomics is very simple. First, sequence DNA from a set of people with a genetic disease. Then compare the sequences against those from healthy people. In theory, the genetic sequence that causes the disease should stand out clearly.²⁴

9. Typical heterogeneous populations create problems, however, for making such comparisons. The first problem encountered is that many different possible mutations could cause an individual to suffer from some of the more common diseases.²⁵ CEO Stefansson explains that common diseases are "common because they are complex ... they probably require the confluence of many genes to cause the disease, but they may also require interactions between genes and the environment."²⁶ Analogous to the adage that "there is more than one way to skin a cat," most scientists theorize multiple

¹⁷ Frick, *supra* note 16.

¹⁸ deCODE genetics, Inc., Form 10-Q, at 1 (Nov. 14, 2001) [hereinafter deCODE 10Q]. As part of the regulations governing the secondary markets in the United States, the Securities & Exchange Commission requires periodic filings for public companies. The reports are available free of charge at <http://www.sec.gov/edgar.shtml>.

¹⁹ Grose, *supra* note 12.

²⁰ See, e.g., Kunzig, *supra* note 7, at E5.

²¹ Enserink, *supra* note 5, at 13.

²² See generally BIOSPACE, *Genomics Primer*, at 5, at <http://www.biospace.com/articles/genomics.primer.print.cfm> (July 11, 2000).

²³ See deCODE genetics, Inc., *Company profile*, at <http://www.decode.com/company/profile> (last visited Apr. 4, 2002) [hereinafter deCODE, *Company profile*].

²⁴ Graham Lawton, *Norse Code Holds Key to Genomics*, 18 CHEMISTRY & INDUS. 715 (1997). See also BIOSPACE, *supra* note 22, at 5.

²⁵ Lawton, *supra* note 24, at 715.

²⁶ POPULATION, INC., *supra* note 16, at 52.

mutations can cause a given disease.

10. Even assuming a researcher could hurdle the multiple mutations problem by isolating a single source of mutation among the diseased population, a second obstacle occurs in a heterogeneous population. When the researcher tries to compare the entire DNA sequences of the diseased people to the healthy population, how can she tell what is natural variation and what is a disease-causing sequence?²⁷ Genetic diversity means that the healthy and afflicted people are likely to have very different sequences *throughout* their DNA, not just the area where the diseased gene occurs.²⁸ This problem, which I refer to as the “red herring” problem, further complicates the search for faulty genes.

2. Icelandic History

11. deCODE genetics purports to solve these two problems by relying on the homogeneity of the Icelandic people as well as their extensive genealogical records. According to many sources, Icelanders today descend mainly from Norse and Irish settlers who colonized the country in the 800s.²⁹ Geographically isolated, the Norse Vikings married amongst themselves to expand the population.³⁰
12. This already limited gene pool further narrowed through a series of catastrophes over the centuries. In the 1400s, the bubonic plague reached the island. The first bout with the Black Death arrived by ship in August of 1402, raging for nineteen months on the island, and killing approximately 50-60% of the population.³¹ In 1494, the plague returned, killing an estimated 30-50% of the remaining Icelanders.³² Two centuries later, another period of genetic disaster struck Iceland. Smallpox reduced the population by a little over a quarter in 1707, striking heavily at young adults. On its heels was a severe famine that reduced the population by another 13%.³³ A final raid on diversity occurred in 1783, when a volcanic eruption in Síða lit afire the landscape.³⁴ Poisonous ash spread across the country and into mainland Europe, possibly reaching as far as France.³⁵ The lava stream from the eruption covered over 580 square kilometers,³⁶ an area about the size of Rhode Island.³⁷ The “Mist Famine,” as it was called, spread throughout the country claiming

²⁷ See Lawton, *supra* note 24, at 715.

²⁸ Another problem that arises is that some mutations in genes do not create any problems with the gene at all. Some substitutions are simply a natural healthy variant of the gene. *Id.*

²⁹ *Id.*; Colin Woodard, *Putting a Price on Icelanders*, S.F. CHRON., Oct. 23, 2000, at A6; Eliot Marshall, *Iceland's blond ambition; genetic research on Icelanders*, MOTHER JONES, May 15, 1998, at 53. Some critics doubt that Icelanders are truly a homogenous population. See Nell Boyce, *Give Us Your Genes*, NEW SCIENTIST, Aug. 12, 2000, at 2222.

³⁰ Marshall, *supra* note 29, at 53.

³¹ See KARLSSON, *supra* note 3, at 111-15.

³² *Id.* at 112-15.

³³ See *id.* at 177-78.

³⁴ *Id.* at 178-80.

³⁵ Historian Karlsson suggests that the eruption may have created the bread shortages in France that contributed to the French Revolution of 1789. *Id.*

³⁶ *Id.*

³⁷ There are 0.386 square miles in one square kilometer. See DAVID HALLIDAY ET AL., PHYSICS A-10 (4th ed. 1992). Rhode Island has a land and water area of 1545 square miles, compared to the 1507 square miles of the Síða

crops, livestock, and approximately 20% of the country's people.³⁸

13. The supply of Icelanders was not replenished from other countries either. According to historical analysis, significant immigration to the island did not occur until World War II.³⁹ Genealogists at deCODE thus maintain that two random Icelanders are sixth or seventh cousins to each other on average.⁴⁰
14. The combination of a small founding gene pool, a narrowing of that pool through epidemics, and a lack of immigration lends credence to the claim that Iceland is the “most homogenous country in the world.”⁴¹ While the Icelandic people are “not like an inbred strain of mice,”⁴² Stefansson admits that, “[w]e are, in a sense, mining the consequences of natural disasters.”⁴³ The CEO commented:

If you think about the isolation of the nation over 1,100 years, and if you think about all the natural disasters, all this misery over the centuries—we are so fortunate that we are a company in a position to turn the consequences of that into value for this nation. In the creation of new knowledge for the entire world. You could argue that it was an attempt to seek some poetic justice for the misery.⁴⁴

3. Advantages of Homogeneity

15. Genetic homogeneity reduces the twin problems of typical genomic studies by making genetic differences between healthy and afflicted individuals more pronounced and by eliminating the problem of multiple mutation sources for a given disease. For the problem that multiple mutations may create a disease, homogeneity makes it more likely that only one genetic culprit is responsible. Icelandic people suffering from a disease often can trace the disease back to a single common ancestor who “founded” the disease in Iceland.⁴⁵ This reinforces the idea that homogeneity can lead to a single source for the genetic mutation. In addition, the homogeneity of the Icelandic people causes less natural variations to exist, keeping researchers on track in the search for the genetic causes of diseases. Homogeneity thus solves the “red herring” problem as well as the multiple mutations problem.⁴⁶
16. deCODE capitalizes on the homogeneity of the Icelandic people by collecting blood

eruption. Netstate, *The Geography of Rhode Island*, available at http://www.netstate.com/states/geography/ri_geography.htm (last visited Apr. 4, 2002).

³⁸ KARLSSON, *supra* note 3, at 180-81.

³⁹ See Frick, *supra* note 16; Woodard, *supra* note 29, at A6; *Roche to Pay deCODE \$200M for DiseaseGene Discovery*, BIOWORLD TODAY, Feb. 3, 1998 [hereinafter *Roche to Pay deCODE*].

⁴⁰ Steve Sailer, *Part 7: Analysis—Immigration and Welfare*, UNITED PRESS INT'L, Sept. 3, 2001, LEXIS, News Library, News Group File, All.

⁴¹ Colin Nickerson, *Perfect for Genetic Research, Some Icelanders Are Wary of Losing Privacy, the Human Factor*, BOSTON GLOBE, Jan. 2, 2000, at A1.

⁴² Frick, *supra* note 16.

⁴³ Marshall, *supra* note 29, at 53.

⁴⁴ Kunzig, *supra* note 20, at E5 (quoting Kari Stefansson).

⁴⁵ Lawton, *supra* note 24, at 715.

⁴⁶ *Id.*

samples from volunteers around the country and entering DNA information from the samples into its own genetic database.⁴⁷ The company finds research subjects willing to donate by accessing a web of collaborating physicians around the country who refer patients to deCODE for study.⁴⁸ After gaining the patient's informed consent, deCODE researchers take a blood sample, isolate the DNA, genotype the results, and enter the genetic information into a database.⁴⁹ Patient identities are encrypted, with the master decoding index tucked into a company safe that can be accessed only when the Icelandic government provides its key.⁵⁰ Through this genetic collection process, which began shortly after incorporation of the company, the company has collected DNA from approximately 50,000 Icelanders.⁵¹ The resulting genetic database can then be cross-referenced with the other databases in deCODE's portfolio: its genealogical database and the health records database.⁵²

B. deCODE's Genealogical Database

17. Despite the media's emphasis on Icelandic homogeneity,⁵³ deCODE heavily relies on its genealogical database that it has created from the rich genealogical records kept by the Icelandic people. The overall homogeneity of the Icelandic people is less relevant if deCODE tends to compare DNA within a given family. If the company does not compare strangers to each other, then it matters little whether or not the strangers are genetically similar. The true benefit of study in Iceland may instead be that deCODE can create extremely large familial clusters, because of the country's passion for genealogy and because Icelanders have tended to stay in Iceland.
18. Extensive genealogical records augment deCODE's search for genetic mutations first by tracing the familial relationships between diseased individuals. Such inheritance patterns among both the living and dead may help reveal the "founder" of the disease, which could lessen the problem of multiple genetic sources for a given disease.⁵⁴ Most importantly, however, knowing a family tree for any given Icelander allows scientists to cluster research subjects into extended family groups.⁵⁵ The company then may proceed to identify the genetic mutation through use of two methods: (1) deCODE scientists can compare the DNA of diseased and healthy individuals who are related to see what is genetically different between them,⁵⁶ or (2) the researchers can compare disease sufferers

⁴⁷ *POPULATION, INC.*, *supra* note 16, at 50.

⁴⁸ *See, e.g.*, Kunzig, *supra* note 7, at E5.

⁴⁹ *Id.*

⁵⁰ *See* Marshall, *supra* note 29, at 53.

⁵¹ *POPULATION, INC.*, *supra* note 16, at 53.

⁵² *Id.*

⁵³ *See, e.g.*, Marshall, *supra* note 29, at 53.

⁵⁴ *See* Lawton, *supra* note 24, at 715.

⁵⁵ *See* *POPULATION, INC.*, *supra* note 16, at 52; *Roche to Pay deCODE*, *supra* note 39; Marshall, *supra* note 29, at 55; Lawton, *supra* note 24, at 715; deCODE, *Company Profile*, *supra* note 23.

⁵⁶ Lawton, *supra* note 24, at 715. This method was used by deCODE in its identification of the chromosomal location of a gene linked to osteoporosis. Press Release, deCODE genetics, Inc., deCODE genetics and Roche Identify Chromosomal Location of Genetic Risk for Osteoporosis at <http://www.decode.com/news/releases/older/item.ehtm?id=5084> (Nov. 14, 2000) [hereinafter Osteoporosis Press Release]. deCODE compared the DNA of 430 sufferers and 600 relatives to isolate the abnormality. *Id.*

who are distantly related to find a genetic similarity that creates the disease condition:

On Iceland, even unrelated people with the same disease often have the exact same mutation.... The patients who have it are not completely unrelated, of course; they all must have inherited it from the same founder, probably from one of the original settlers. And the importance is this: Two otherwise unrelated Icelanders who inherit a mutation from a common ancestor 50 generations back will share a much smaller chunk of DNA than, say, two first cousins who inherit a mutated gene from their common grandfather.⁵⁷

19. By enabling researchers to know whether or not two people are in fact related, genealogy allows deCODE to compare genetic sequences that will have less background noise than in a typical heterogeneous population.
20. Computerization of the genealogical records by deCODE streamlines the creation of family trees for research purposes. In the late 1990s, deCODE began cataloguing the bloodlines of all present and past Icelanders, a total of somewhere between 625,000 to 750,000 people who have lived in Iceland over its 1100 years.⁵⁸ With over 560,000 names and relationships already entered into the database, the project is nearing completion.⁵⁹ While deCODE plans to open the database to the public for any purpose, the current use of the genealogical database empowers the company to quickly identify “founders” and divide research subjects into suitable clusters for analysis.⁶⁰

C. deCODE’s Most Controversial Collection: Health Records from the Icelandic People

21. The unique homogeneity and genealogical factors of the Icelandic people differentiate deCODE from many biotechnology companies, but the corporation’s most unusual resource is its access to the health records of the Icelandic people. In January 2000, deCODE received an exclusive right to utilize Iceland’s health records for its own private commercial goals.⁶¹
22. As deCODE computerizes the health information, it can cross-reference the health database with its genealogical database and the genetic data received from individual patients who have donated blood to deCODE projects.⁶² Once completed, the megadatabase would become a “powerful tool for pharmacogenomics”⁶³ that optimistically would “constitute all the spadework that would ever need to be done to

⁵⁷ Kunzig, *supra* note 7, at E5. See also deCODE genetics, Inc., *Products and Services: Genealogy Approach*, at <http://www.decode.com/products/ga/> (last visited Apr. 4, 2002) [hereinafter deCODE, *Genealogy Approach*].

⁵⁸ See *Norse Code*, THE ECONOMIST, Dec. 5, 1998, at 99; Kunzig, *supra* note 7, at E5.

⁵⁹ See Kunzig, *supra* note 7, at E5; *Norse Code*, *supra* note 58, at 99.

⁶⁰ See deCODE, *Genealogy Approach*, *supra* note 57; Kunzig, *supra* note 7, at E5.

⁶¹ OPERATING LICENSE, *supra* note 6, at 3, 18.

⁶² E.g., Woodard, *supra* note 29, at A6; *Roche to Pay deCODE*, *supra* note 39.

⁶³ *Roche to Pay deCODE*, *supra* note 39.

launch any genetic study in Iceland.”⁶⁴

1. Background on Health Records and Health Records Database

23. Compiled since 1915, the health records of Icelanders contain a wealth of information about most of the Icelandic population.⁶⁵ The results of laboratory tests, diagnoses of disease, treatments assigned, and the outcome of those treatments all comprise part of the information gathered over the years by doctors and hospitals in Iceland.⁶⁶ In addition, the National Health Service tracked patients with certain diseases into specialty institutions, making it even easier for deCODE to collect information about a given condition.⁶⁷ Described in a bill before the Icelandic Parliament as a “national resource,” the health data has been systematically recorded with “much work ... devoted to the quality of the records.”⁶⁸ Such health information remained largely decentralized, however, before the passage of the Health Sector Database Act (the Health Database Act or the Act).⁶⁹ While many separate electronic databases existed in Iceland, no single comprehensive database integrated the data sets, let alone incorporated non-computerized files.⁷⁰
24. The passage of the Health Database Act authorized the government of Iceland to grant permission to a licensee to establish and maintain a single database for patient health records. The Icelandic Parliament, the Alþingi, approved the Health Database Act by nearly a two-thirds margin on December 17, 1998, following months of public and legislative debate.⁷¹ Proposed by deCODE’s own Kari Stefansson, the Act authorizes the creation of a centralized database for health information that cannot be traced to a specific individual.⁷² The Act presumed the consent of patients to release their records to

⁶⁴ Kunzig, *supra* note 7, at E5.

⁶⁵ Woodard, *supra* note 29, at A6.

⁶⁶ *Id.*

⁶⁷ See Kunzig, *supra* note 7, at E5. For example, in June 2001, deCODE contracted with the Icelandic Cancer Society to gain access to information about the patients listed on its registry. *deCODE genetics to Use Iceland’s Patient Register to Aid Cancer Research*, NORDIC BUS. REP., June 27, 2001.

⁶⁸ *Bill on a Health Sector Database*, 123rd Iceland Parl. Notes to Bill I.2 (1998-99)

<http://government.is/interpro/htr/htr.nsf/pages/gagnagr-ensk> (last visited Apr. 4, 2002) [hereinafter *Health Database Bill*]. The *Health Database Bill* was submitted to the Alþingi for consideration in October 1998. The bill contains an explanatory section that gives the reasons for voting in favor of the bill, as well as clarifying the scope of some of the provisions. This paper refers to both the *Health Database Act* and the final act passed by the legislature, the Act on a Health Sector Database.

⁶⁹ See No. 139, *Act on a Health Sector Database*, 123rd Iceland Parl. Art. 10 (1998-99)

<http://government.is/interpro/htr/htr.nsf/pages/gagnagr-log-ensk> (last visited Apr. 4, 2002) [hereinafter *Health Database Act*]; Jonatansson, *supra* note 13, at 37.

⁷⁰ See Jonatansson, *supra* note 13, at 37; *Health Database Bill*, *supra* note 68, at Notes to Bill I.2.

⁷¹ *Health Database Bill*, *supra* note 68; *POPULATION, INC.*, *supra* note 16, at 53; Enserink, *supra* note 5, at 13. CEO Stefansson claims that the nine-month debate generated 700 newspaper articles and 140 television and radio shows. Polls at time of the passage of the Act show a 75% support rate, which has risen to 91% in later polls. *POPULATION, INC.*, *supra* note 16, at 50.

⁷² *Health Database Bill*, *supra* note 68, at Notes to Bill I.2, III.2; *Health Database Act*, *supra* note 69, at art. 1-3. According to the Act, the database entries should contain only “non-personally identifiable” data, meaning that the patient who gave the data cannot be identifiable “directly or indirectly, especially by reference to an identity number, or one or more factors specific to his physical, physiological, mental, economic, cultural or social identity.” *Health Database Act*, *supra* note 69, at art. 1-3. In the *Health Database Bill*, the Parliament assumed that entries

deCODE. Individuals thus must affirmatively opt out in order to prevent their data from being recorded in the health sector database.⁷³

25. Under the terms of the Act, a private licensee approved by the Icelandic Ministry of Health may construct and manage the database under a license that may last up to twelve years.⁷⁴ The licensee is not granted immediate access to the health records, however. Instead the licensee must contract with health institutions, doctors, and hospitals to gain access to the medical records for transfer onto the centralized database after the primary caregiver has properly coded the information.⁷⁵ deCODE genetics received the first exclusive license granted under the Health Database Act in January 2000.⁷⁶ Barring revocation, deCODE's license will continue for twelve years, the maximum allowed by the Act.⁷⁷

2. Economic Provisions of Health Database Act

26. The Health Database Act establishes a delicate quid pro quo arrangement in which the licensee funds the construction of the database in exchange for the opportunity to use the database for private commercial profit. Such exploitation of a public resource by a private corporation generates a significant amount of controversy concerning the database.⁷⁸
27. During its tenure as licensee, deCODE may “use the data on the database for ... financial profit” limited only by certain key conditions demanded by the Icelandic government.⁷⁹ In addition to allowing private profit from the operating license, deCODE also enjoys an effective monopoly over use of the database; only the Ministry of Health and Director General of Public Health have access to the statistical data for reporting, licensing and policy-making purposes.⁸⁰ A final bonus for deCODE is that the Act expressly allows the company to connect the health database to genetic and genealogical databases, paving the path for the creation of the megadatabase ultimately envisioned by deCODE.⁸¹

would consist mainly of data that could be put in numerical form. *See Health Database Bill, supra* note 68, at Notes to Bill III.2.

⁷³ *Health Database Act, supra* note 69, at art. 8.

⁷⁴ *Id.* at art. 4-5.

⁷⁵ *Id.* at art. 7.

⁷⁶ OPERATING LICENSE, *supra* note 6, at 3, 18.

⁷⁷ *Id.* at 18.

⁷⁸ *See* discussion *infra* Section III.A.1.

⁷⁹ *Health Database Act, supra* note 69, at art. 10.

⁸⁰ *Id.* at arts. 4, 9. The original bill contained a more nuanced version of Article 9, requiring a government committee to review research requests for access to the database by scientists and other third parties. The committee could deny access if the research would “have an adverse effect upon the licensee's commercial interests.” *Health Database Bill, supra* note 68, at art. 9. The *Health Database Act* deleted those portions of the *Health Database Bill*, leaving the ultimate contours of scientific access undefined.

⁸¹ *Health Database Act, supra* note 69, at Art. 10. Under the Act, “[t]he licensee shall develop methods and protocols ... to ensure confidentiality in connecting data from the health-sector database, from a database of genealogical data, and from a database of genetic data.” *Id.* *See also* Enserink, *supra* note 5, at 13. Heavy criticism of the linkage prompted the Icelandic Minister of Education, Science and Culture, Björn Bjarnason, to defend Iceland's actions in a statement to an international bioethics forum:

It has been criticised that DeCODE [sic] will have the possibility to link information in the Health Sector Database with genealogical and genetic information. However, this linking is only

28. Many of the conditions imposed upon deCODE center on the monetary costs of the database. In terms of direct financial costs, the Health Database Act requires deCODE to pay all of the costs associated with the construction and maintenance of the database, even though the database ultimately reverts back to the Icelandic government at the termination of the license.⁸² Estimates of the costs of creating the database, which include paying workers for data entry, range from 10.5 to 19.3 billion krónur, or approximately \$10.5 to \$19.3 million.⁸³ Additionally, the company is responsible for a host of secondary costs. The company pays for the preparation of its licenses with Iceland,⁸⁴ monitoring and oversight by government committees,⁸⁵ and publicity efforts by the Iceland government to inform patients of their rights to opt out of the database.⁸⁶
29. The Icelandic government also receives an annual fee from deCODE as part of the license agreement, along with a minute share of company profits. Each year, deCODE must pay Iceland 70 million krónur, or a little over \$700,000.⁸⁷ The general fee is used by the government to “promote health care and for research and development.”⁸⁸ The fee may be adjusted, however, depending on the circumstances of the company. After 2006, deCODE may request reduction of the fee to as little as 50 million krónur (approximately \$500,000) if the “basis of operations and business plans of [deCODE] have changed substantially and it is foreseeable that the company will not return a profit over the next 2 to 3 years.”⁸⁹ If, on the other hand, deCODE earns a profit during its license term, the company must pay 6% of its pretax profits to the Icelandic government.⁹⁰ Such a profit share is limited to 70 million krónur, however, making the maximum fees paid by deCODE total 140 million krónur, or approximately \$1.4 million dollars.⁹¹

temporary and will be done according to procedures approved and overseen by the Data Protection Authority, and importantly, no genetic or genealogical information is allowed to enter the Centralised Health Sector Database. I ask you also to bear in mind that the genealogical information in DeCODE’s [sic] genealogical database, “The Book of Icelanders” is constructed from publicly available information and importantly the genetic information that DeCODE [sic] has in their genetic database originates from biological samples obtained with written informed consent given by the donor.

Björn Bjarnason, *UNESCO, Round Table on Bioethics: Paris 22-23 Oct. 2001*, at The Icelandic Health Sector Database, <http://www.bjorn.is/safn.view.php?id=713&list=greinar> (Oct. 22, 2001).

⁸² OPERATING LICENSE, *supra* note 6, at arts. 10.1–10.5. Iceland requires that deCODE transfer all the intellectual property rights necessary to create and operate the database after termination of the license, including making arrangements to transfer copyright rights to software as well as enabling the government to have “user licenses” from parties that contract and provide services and software to deCODE. *Id.* at arts. 8.3-8.11.

⁸³ *Health Database Bill*, *supra* note 68, at Notes to the Bill § I.2. As of April 4, 2002, the exchange rate for the Icelandic krónur was 99.47 krónur per U.S. dollar. eSignal, *Foreign Exchange Rates—Europe*, Apr. 4, 2002, at <http://www.dbc.com/cgi-bin/htr.exe/dbcfiles/fxEUROPt.html> (last visited Apr. 4, 2002).

⁸⁴ *Health Database Act*, *supra* note 69, at art. 4.

⁸⁵ *Id.*

⁸⁶ *Id.* at arts. 4, 8.

⁸⁷ Agreement Relating to the Issue of an Operating Licence [sic] for the Creation and Operation of a Health Sector Database, Jan. 21, 2000, art. 4, Minister for Health & Soc. Sec.-Íslensk erfðagreining ehf., [http://www.raduneyti.is/interpro/htr/htr.nsf/Files/Aggreement/\\$file/AGREEMENT-english.pdf](http://www.raduneyti.is/interpro/htr/htr.nsf/Files/Aggreement/$file/AGREEMENT-english.pdf) [hereinafter deCODE Fee Agreement].

⁸⁸ *Id.* at art. 3.

⁸⁹ *Id.* at art. 5.

⁹⁰ *Id.* at art. 6.

⁹¹ *Id.*

30. Additional provisions serve to maximize the economic health of Iceland indirectly by tethering many of deCODE’s research activities to the island. Even though deCODE is allowed to remain a Delaware corporation, the Health Database Act imposes strict rules concerning the location of the health sector database.⁹² Article 5 of the Health Database Act requires that the database exclusively remain in Iceland,⁹³ and the operating license further extends the territorial requirements by requiring that data processing also occurs exclusively in Iceland.⁹⁴ Collaborative efforts with non-Icelandic entities are discouraged as well. The operating license forbids deCODE from either transferring the health records or linking them to other databases or projects outside Iceland without governmental permission.⁹⁵ The express purpose of the tethering provisions is “to ensure that it is possible to enforce regulations, which are to ensure confidentiality.”⁹⁶ By limiting deCODE’s tendency to defect from Iceland, Icelanders can better monitor the activities of deCODE. In addition, tethering may also reap ancillary benefits for the Icelandic economy, including increased employment opportunities for its people, tax revenues, and publicity that may draw future business to the area.⁹⁷

3. Privacy Provisions of Health Database Act

31. The Health Database Act presumes that all Icelanders consent to having their health records transcribed onto the health database. Patients must affirmatively opt out through a petition process in order to avoid inclusion.⁹⁸ The justifications offered for choosing the presumed consent provision have both a practical and a legal dimension.
32. According to the Alþingi, the information collected in the health records belongs to neither the individual patient nor the health institution that initially recorded the data.⁹⁹

⁹² *Health Database Bill*, *supra* note 68, at principal amends. § 3.

⁹³ *Health Database Act*, *supra* note 69, at art. 5.

⁹⁴ OPERATING LICENSE, *supra* note 6, at art. 3.3.

⁹⁵ *Id.*

⁹⁶ *Health Database Bill*, *supra* note 68, at Notes to the Bill § III.2.

⁹⁷ *Id.* at Notes to the Bill § I.2 (suggesting that the database may develop Iceland’s high tech industry and attract new business). *See also* OECD ECONOMIC SURVEYS—ICELAND, *supra* note 11, at 88 (citing deCODE’s employment in Iceland, an increase in research and spending in the high tech sector, and the lack of tax breaks for such new ventures).

⁹⁸ *Health Database Act*, *supra* note 69, at art. 8.

⁹⁹ *Health Database Bill*, *supra* note 68, at Notes to the Bill § I.2. The Bill states that “[d]ue to the nature of the data and their origin they cannot be subject to ownership in the usual sense. Institutions, companies or individuals cannot therefore own the data. They exist primarily due to the treatment of patients.” *Id.* In this manner, Iceland deviates from what may be expected by the labor theory or the personality theory of intellectual property law. For a comprehensive review of major theories behind intellectual property rights, see generally William Fisher, *Theories of Intellectual Property*, in NEW ESSAYS IN THE LEGAL AND POLITICAL THEORY OF PROPERTY 168 (Stephen R. Munzer ed., 2001). Under the labor theory, the mixing of one’s labor with a natural resource creates intellectual property rights in that resource. *Id.* As applied to patient health records, the labor theory might suggest that property rights should vest in the health workers and health institutions who labored upon the raw material (the patient and their disease) to transform that resource into a useful product. The labor theory is one of the main foundations for allowing genes, computer algorithms, and business methods to be patented in the United States. Beginning with the decision of the United States Supreme Court in *Diamond v. Chakrabarty*, the United States has allowed patenting for “anything under the sun that is *made by man*.” *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (quoting legislative history) (emphasis added). On the other hand, personality theory would appear to grant rights to the individual patient. Under Fisher’s analysis of personality theory, intellectual property rights attach to protect

By denying the existence of a traditional property right in the records, the government then could step in and allocate property rights as it saw fit. Obligated to fulfill its “duty” to explore the use of the health records, the Alþingi then made a decision between informed and presumed consent on more practical grounds.¹⁰⁰ After hypothesizing that a nonpersonally identifiable database would not violate European Union laws requiring informed consent,¹⁰¹ the Alþingi settled on a presumed consent model:

In the first place, it is possible to create a database of personally identified or identifiable data, which would be entered on the database with the consent of all the individuals in question. The advantage of this is that data can easily be traced to individuals if necessary for health or other reasons. The disadvantage is that participation might be less, so that the database would be of less value. Clearly it would cost great effort, time and money to gain consent from every individual in a data collection envisaged here. This finance could otherwise used [sic] to ensure confidentiality and build up the dispersed databases.

In the second place, a non-personally identifiable database may be built up. In this case, consent is not required, as identification is coded and data cannot be traced back. The disadvantage is that it is not possible to trace individuals who might be in need of health care. This would have to be done by the conventional methods, i.e. via health institutions. The advantage is that confidentiality (personal privacy) would be more effective, and it would be more likely that comprehensive data could be collated. It is also more likely that finance would be available for building up a database of this kind.¹⁰²

33. The parliament thus chose an encrypted presumed consent model in order to reduce costs, increase the amount of data in the database, and ensure tracking of patients for health care purposes. The controversial structure of presumed consent created a heightened need to protect the confidentiality of the patients; because every patient will have their data entered into the database under the default scenario, the government believed it should at least ensure that the sensitive information in those records is not traceable to a specific patient.¹⁰³ The database could not have been anonymous, either. New updates on patients would be continuously added to the database, a process that requires linking the new data to a patient profile.¹⁰⁴ Because of the presumed consent nature of the Health Database Act and the need for encrypted rather than anonymous data entry, the Data Protection Committee has established a host of provisions, subsequent agreements, and protocols

fundamental needs or interests. Fisher, *supra*. Piece of mind, privacy, and the ability to be “recognized as a free agent” may justify extending intellectual property rights to patients. *Id.*

¹⁰⁰ *Health Database Bill*, *supra* note 68, at Notes to the Bill §§ I.2, III.3.

¹⁰¹ *Id.* at Notes to the Bill § II.

¹⁰² *Id.* at Notes to Bill the § III.3.

¹⁰³ *Id.*

¹⁰⁴ See Bogi Andersen & Einar Arnason, *Iceland's Database Is Ethically Questionable*, 318 BRITISH MEDICAL JOURNAL 1565 (1999).

designed to protect the sensitive information located in health records.¹⁰⁵

34. Outlining the protection process, Article 7 of the Health Database Act first requires that records be coded by their current custodians, i.e. by the staff of the health institution itself or by other private health workers not associated with deCODE.¹⁰⁶ Identification that may “out” a patient is encoded one-way, under the terms of the Act.¹⁰⁷ The Encryption Agency operated by the Data Protection Commission codes such personally identifiable data before transferring the data to deCODE.¹⁰⁸
35. As data is entered into the health sector database, the Health Database Act envisions extensive use of the information by deCODE, allowing the company free reign to develop treatments, diagnoses, and other commercial goods from the license.¹⁰⁹ Once more, however, the company must guard confidentiality of the patients. Employees of deCODE must sign confidentiality agreements,¹¹⁰ and the processing of the health records database must ensure the non-identifiability of the individual patient.¹¹¹ This is a formidable task given the tiny size of the country and the possibility that recognition of an individual may occur even when only basic data is known about the patient.¹¹² Article 10 also extends the confidentiality requirement if and when deCODE links its genealogical and genetic databases to the health records database.¹¹³ The likelihood of “indirect identification” significantly increases further under such linkage, prompting critics to scoff at attempts to protect patient confidentiality.¹¹⁴ To ensure compliance with the confidentiality

¹⁰⁵ See, e.g., *Health Database Act*, *supra* note 69, at art. 7; ADMIRAL MGMT. SERVICES LTD., SECURITY TARGET FOR AN ICELANDIC HEALTH DATABASE, [http://www.stjr.is/interpro/htr/htr.nsf/Files/securitytarget.pdf/\\$file/SecurityTarget.pdf](http://www.stjr.is/interpro/htr/htr.nsf/Files/securitytarget.pdf/$file/SecurityTarget.pdf) (Jan. 5, 2000) (providing the Icelandic Data Protection Commission with a highly technical guide to the IT system that should be developed for entering and accessing the database). The Data Protection Commission has also issued protocols. THE ICELANDIC DATA PROTECTION COMMISSION, TECHNOLOGY, SECURITY, AND ORGANISATION TERMS OF THE ICELANDIC DATA PROTECTION COMMISSION IN RELATION TO A HEALTH-SECTOR DATABASE, CF. ACT NO. 139/1998, [http://www.stjr.is/interpro/htr/htr.nsf/Files/AppendixG/\\$file/GeneralSecurityTerms.pdf](http://www.stjr.is/interpro/htr/htr.nsf/Files/AppendixG/$file/GeneralSecurityTerms.pdf) (Jan. 19, 2000) (setting up security measures, such as the creation of an Encryption Agency) [hereinafter DATA PROTECTION COMMISSION TECHNOLOGY, SECURITY, AND ORGANIZATION TERMS].

¹⁰⁶ *Health Database Act*, *supra* note 69, at art. 7.

¹⁰⁷ *Id.*

¹⁰⁸ DATA PROTECTION COMMISSION TECHNOLOGY, SECURITY, AND ORGANIZATION TERMS, *supra* note 104, at art. 4.

¹⁰⁹ *Health Database Act*, *supra* note 69, at art. 10. Data extracted from the health records database “may be used to develop new or improved methods of achieving better health, prediction, diagnosis, and treatment of disease, to seek the most economic ways of operating health services, and for making reports in the health sector.” *Id.*

¹¹⁰ *Id.* at art. 11.

¹¹¹ *Id.*

¹¹² Jonatansson, *supra* note 13, at 49-51. The possibility of indirect identification may be quite high given the sparse population. *Id.* at 49. Given the relative rarity of some diseases, only a few people may be infected in a given part of the country. The argument is then that a data entry worker or scientist utilizing the data may actually have a good clue who the patient is, despite any encryption, simply through knowing neutral factors like gender, age, town, and the disease of the person. *Id.* For a similar critique, see Andersen & Arnason, *supra* note 68, at 1565.

¹¹³ *Health Database Act*, *supra* note 69, at art. 10.

¹¹⁴ See Andersen & Arnason, *supra* note 104, at 1565. Often described as “closeknit,” Icelanders are “quick to establish connections when introduced, by delving into their family trees.” DISCOVERY CHANNEL, *supra* note 2, at 340. Social customs create informality and a participatory nature in society. As one immigrant explained, “Everyone is equal, so everyone is important. Everyone is a participant in society, it isn’t possible to opt out, to deny your responsibility.” *Id.* at 75. The Icelandic language also does not have titles like “Mr. and Mrs.,” but instead Icelanders refer to *everyone* by their first name; even the president would be called “Ólafur”. *Id.* at 74, 340 (the President’s full

requirements associated with processing in the health records database, an independent expert on security must pre-approve the procedures for such access.¹¹⁵

36. Given the importance of the confidentiality provisions to the perceived fairness of the database, the Icelandic government may enforce the requirements in a variety of ways. The harshest sanction is revocation of the license, a power granted to the government should deCODE fail to correct violations of the license.¹¹⁶ Violations may also carry criminal penalties of up to three years in prison, along with fines.¹¹⁷ Financial losses associated with breaches of confidentiality also are compensable under the Act, with deCODE ultimately responsible for the actions of its employees.¹¹⁸ Finally, deCODE has agreed to indemnify the Icelandic government for any litigation and judgments that occur because of the creation or use of the health database.¹¹⁹ Such a sweeping indemnification shifts the risk of confidentiality breaches squarely onto deCODE.

D. Fitting It All Together: Ultimate Goals of deCODE

37. If the company can successfully maneuver around the limitations on the health records database, deCODE will combine that database with its genetic and genealogical databases. Even with only its genetic and genealogical databases, however, deCODE has a large number of options for generating products and potential profits. At a minimum, deCODE can sell access to any or all of its databases to other biotechnology and pharmaceutical companies for their own research goals.¹²⁰ In addition deCODE may license the software and other technologies it develops to mine the databases.¹²¹ The licensees could then use the deCODE software to extract useful information from other genetic databases gathered separately throughout the world.
38. As its main goal, however, deCODE hopes to derive profit from its own research and discovery of genetic mutations related to disease. Once a gene has been identified, deCODE could choose to license the gene to another company, develop its own diagnostics to test for the mutation, or embark on designing a drug to counteract the effects associated with the faulty gene. Any of those three options require the isolation of the genetic mutation, a painstaking process of elimination. deCODE first must determine which of the twenty six human chromosomes appears to be linked to the presence of the disease.¹²² The researchers then must identify which region, or locus, of the chromosome

name is Ólafur Ragnar Grímsson). Accordingly, telephone directories are alphabetized according to a person's first name, and often contain a person's occupation right alongside. *Id.* at 340. Such a society may become more familiar with each other and more capable of recognizing each other with minimal details disclosed.

¹¹⁵ MINISTRY FOR HEALTH & SOC. SEC., ICELAND, GOVERNMENT REGULATION ON A HEALTH SECTOR DATABASE No. 32/2000 Art. 5 at <http://government.is/interpro/htr/htr.nsf/pages/Govreg32-2000> (Jan. 22, 2000).

¹¹⁶ *Health Database Act*, *supra* note 69, at art. 13.

¹¹⁷ *Id.* at art. 14.

¹¹⁸ *Id.* at art. 17.

¹¹⁹ DECODE FEE AGREEMENT, *supra* note 87, at art. 15; deCODE 10Q, *supra* note 18h, at 24.

¹²⁰ deCODE genetics, Inc., *Company Business Model*, at II, at <http://www.decode.com/company/model> (last visited Sept. 20, 2002) (offering subscriptions to the databases constitutes one of the "key elements" to deCODE's business strategy) [hereinafter deCODE, *Company Business Model*].

¹²¹ *Id.* at IV (marketing software tools will also be part of the business model).

¹²² deCODE, *Company Profile*, *supra* note 23.

is responsible.¹²³ The final step of the process is to examine the locus until scientists can hone in on a specific gene,¹²⁴ one of 100,000 possible in the human genome.¹²⁵

39. Once a disease gene is identified, deCODE then has a genetic sequence that may be licensed or used internally by the company. Another company, or deCODE, may develop a test kit for that sequence to identify tendencies toward the disease.¹²⁶ Such diagnostics tests are a source of immediate revenue for most genetics companies, and can provide large payoffs if successful.¹²⁷ Diagnostics generate only a fraction of the wealth of a drug, however. With a genetic sequence, deCODE can attempt to design a drug or therapy based upon the mutation it discovered.¹²⁸ Such “rational drug design” continues to be the elusive holy grail of many small pharmaceutical companies.¹²⁹ According to scientists who attempt rational drug design, knowing what a mutation does in the body may allow the researcher to counter the negative effects of the mutation.¹³⁰ For both disease diagnostic kits and medicines, one potential problem is that the mutation that forms the basis for such products may not be common to the rest of the world. In other words, if deCODE develops a cure or test for a mutation that Icelanders have, there is no guarantee that the product will work anywhere other than Iceland.¹³¹
40. When deCODE began in 1997, the public was just starting to debate whether or not genetic mining was in the public interest. The term bioprospecting tended to be associated with the exploitation of plants rather than with the exploitation of people. deCODE did not just tiptoe into the population genomics arena—the company started with, and continues to operate under, an extremely ambitious plan for scientific and business success. From their bold move to study an entire nation to the acquisition of the controversial health records database, deCODE tests the limits of bioprospecting. An examination of the success of such a battle plan follows.

¹²³ *Id.* The human genome has about 3 billion base-pairs. Base-pairs are the “genetic letters” that spell out genes. Robert Matthews, *Strange But True: Clues to Disease Lie in the Blood of the Vikings*, THE SUNDAY TELEGRAPH, Sept. 21, 1997, at 20. In visual terms, base-pairs comprise the ladder steps that one sees in double-helix portrayals of DNA.

¹²⁴ deCODE, *Company Profile*, *supra* note 23.

¹²⁵ See Matthews, *supra* note 123, at 20.

¹²⁶ Kim Coghill, *deCODE, Roche Enter New Deal on DNA-Based Products*, BIOWORLD TODAY, Mar. 7, 2001 (reporting that Roche and deCODE would “develop an integrated suite of new diagnostic products and services” based upon deCODE’s genetic research to date).

¹²⁷ See Ronald Kotulak, *Taking License with Your Genes: Biotech Firms Say They Need Protection*, CHI. TRIB., Sept. 12, 1999, at C1.

¹²⁸ deCODE, *Company Business Model*, *supra* note 120, at I (making drug target discovery one of their strategies).

¹²⁹ David Pilling, *Uncertainty Prefaces Genetic Book of Life*, FINANCIAL TIMES (LONDON), Dec. 18, 2000 (quoting Greg Parekh, the co-head of European health-care at Deutsche Bank, who said, “People speak of genomics as the Holy Grail, [b]ut few appreciate how far having a gene is away from having a target, let alone a drug.”)

¹³⁰ Kotulak, *supra* note 127. If a mutation means that a person’s body does not produce enough of a certain protein, that protein may be supplied. Similarly, if the mutation results in an overabundance of a protein, then researchers may try to block that production with medicines and drugs specifically designed to interact with the promiscuous protein.

¹³¹ deCODE 10Q, *supra* note 18, at 22; Lawton, *supra* note 24, at 715 (reporting an Oxford University professor’s comments that deCODE “could end up knowing lots about Icelanders but zero about anybody else”).

III. The Current State of Affairs: deCODE and Iceland

41. Passage of the Health Database Act jolted expected notions concerning privacy, genetics research, and the role of government in accommodating technological development. The sheer novelty of the opt-out system, combined with the cutting edge theory of population genomics as applied by deCODE, made *ex ante* rational evaluation of the bargain extremely difficult. One commentator saw the intellectual exploration associated with deCODE as thrusting mankind “into unknown and potentially perilous territories,”¹³² a statement that reflected the widespread unease with both the ends and the means that Iceland was pursuing. In a sense, the world was holding its breath as deCODE “us[ed] the entire nation of Iceland as one giant pharmacogenetic laboratory,” perhaps fearing what monster may emerge.¹³³
42. At the time of the Act’s passage, one could only speculate on the effect of the Health Database Act and the success of deCODE from a commercial or moral perspective. Was the science solid? Would the confidentiality provisions accomplish their goal? How much should Iceland demand? How much should deCODE give? Now that a few years have time-tested the business model upon which deCODE relies, we can evaluate how deCODE and Iceland have fared, to see what has actually happened as they settle into their unique relationship. This Section looks at the political, scientific, and economic hurdles that deCODE has conquered and the ones that are still left. It also examines what Iceland has gained from housing deCODE and providing support. As other countries and population groups face the same questions about technology, privacy, corporate success, and government intervention, the preliminary results from the Icelandic experiment may prove useful.

A. Present Condition of deCODE

43. Culminating in a patent filing frenzy earlier this year, deCODE has spent its first five years announcing significant scientific breakthroughs at a regular pace. The company’s business policy similarly evidences a focus on success, with a proliferation of strategic alliances, research agreements, and even a business acquisition. Political and technological obstacles impede the expansion of the health records database, however, retarding the expectations of the company and Iceland itself.

1. Political and Legal Trouble with the Health Database Act

44. Because of the extraordinary nature of the Health Database Act, a discussion of deCODE’s current state should begin by first examining the ramifications of the Act on the company and its corporate health. The passage of the Act and the designation of deCODE as licensee rocketed the company into controversy. To this day, the company

¹³² Jonatansson, *supra* note 13, at 65.

¹³³ Laura Common, *Custom-Tailored Medicines Coming of Age: How Treating Diabetes and Other Ailments Will Change by 2010*, MEDICAL POST, May 22, 2001, at 39; *see also, e.g.*, Aline Sullivan, *Iceland, a Natural Genetics Lab*, INT’L HERALD TRIB. (Neuilly-sur-Seine, France), July 1, 2000, at 18 (commenting that “the company has generated more controversy in Iceland about privacy than medical discoveries”); *POPULATION, INC.*, *supra* note 16, at 50 (quizzing CEO Stefansson about the health records database).

faces pressure from concerned ethical groups, private individuals, and health care providers, all of whom bitterly attack the Health Database Act for its opt-out provision. Not content with flinging angry words, Icelandic ethicists threaten to dismantle the Act through litigation,¹³⁴ and doctors invoke passive resistance by pledging to withhold the health records of their patients.¹³⁵ Put simply, the substantial negative, bewildered, cynical, and indignant responses raise questions about whether continuing the health database on an opt-out basis truly adds enough value to the company to make up for the headache.

45. While bad press may be better than no press at all for a fledgling company, the “visceral” reaction against the “very Orwellian” presumed consent provisions of the database may work against deCODE.¹³⁶ The company needs public trust to receive blood donations and other medical information from Icelanders.¹³⁷ The viciousness of the debate is apparent on both sides. Stefansson reportedly called his critics “hyenas and backbiters,”¹³⁸ while a slightly more diplomatic supporter of the health database referred to the protestors as “unduly paranoid.”¹³⁹ Lashing back, the opponents of deCODE have accused the company of having had an “incestuous relationship” with the Icelandic government and warn that the country may be heading down the same eugenics path as the Nazis.¹⁴⁰ Around the world, newspaper articles,¹⁴¹ television shows,¹⁴² scientific

¹³⁴ deCODE 10Q, *supra* note 18, at 24; *POPULATION, INC.*, *supra* note 16, at 50.

¹³⁵ deCODE 10Q, *supra* note 18, at 23; Woodard, *supra* note 29, at A6.

¹³⁶ Martin Enserink, *Physicians Wary of Scheme to Pool Icelanders’ Genetic Data; Database of Health Records Would be Granted to Private Company for Analysis*, 281 *SCI.* 890 (1998) (quoting Stefansson, who acknowledged the negative way that the public may perceive deCODE’s projects).

¹³⁷ Andy Coghlan, *Selling the Family Secrets*, *NEW SCI.*, Dec. 5, 1998, at 20; Marshall, *supra* note 29, at 53 (Stefansson commented that “[Our] relationship with the population is the most important thing we have.”).

¹³⁸ Petur Hauksson, *Chairman of Mannvernd, Criticizes the Reaction of Health Authorities*, *MORGUNBLADID*, Feb. 19, 2000, at 10 (reporting that Stefansson issued the slur at those who attacked deCODE), *available at* Mannvernd, *News Archives*, <http://www.mannvernd.is/english/index.html>.

¹³⁹ Enserink, *supra* note 5, at 13.

¹⁴⁰ See Amedeo Santsuosoo, *The Right to Genetic Disobedience: The Iceland Case*, Oct. 15, 2000, *available at* Mannvernd, *News Archives*, <http://www.mannvernd.is/english/index.html>; *see also* Enserink *supra* note 5 (reporting comments by Social-Democrat Ossur Skarphedinsson, chair of the health panel, that deCODE had a “stronghold” on the Alþingi). Attacks on Stefansson are also common. For example, one commentator blamed the scope of the controversy on the CEO:

And if the unwanted debate sometimes took on ridiculous proportions, I find it necessary to say that the remarkably arrogant Kari Stefansson bears much of the responsibility for this. He consistently trivialized serious issues, persistently lied, and rarely gave his critics little more than a dismissive sneer. *It is necessary* that the leaders of genomics enterprises *not* be volcanic, volatile, ambitious, impatient, arrogant, or snide.

Mike Fortum, *Experiments in Ethnography and its Performance*, Feb. 12, 2000, *available at* Mannvernd, *Articles dealing with the health sector database*, <http://www.mannvernd.is/english/index.html> (last visited Apr. 4, 2002).

¹⁴¹ *See generally*, e.g., Crenson, *supra* note 29, at 6; Lewontin, *supra* note 13, at A19.

¹⁴² *See*, e.g., Richard Gizbert & Barbara Walters, *Nightline: A Genetic Bank* (ABC television broadcast, May 13, 1999); Ed Bradley, *Genes; 60 Minutes: Ethics of Allowing deCODE, a Genetic Research Company, Exclusive Access to Nearly All Medical Records of Iceland’s 280,000 People in Order to Create a Database* (CBS television broadcast transcript, Apr. 22, 2001).

journals,¹⁴³ and many websites¹⁴⁴ have all raised concerns about the Health Database Act and deCODE's role.

a. Privacy and Autonomy Arguments

46. From the debate two distinct strands of protest appear, one concerning privacy rights and the other involving ideas about self-autonomy.¹⁴⁵ In discussing their choice of a presumed consent encryption system for the database, the Alþingi focuses entirely on issues of keeping the database secure.¹⁴⁶ Both the Icelandic government and deCODE concern themselves heavily with protections designed to ensure the confidentiality of patients. Upon their rationale, a well-working encryption system would protect Icelanders from discriminatory employers,¹⁴⁷ evil computer hackers,¹⁴⁸ and those “kooks in the insurance industry,”¹⁴⁹ as Stefansson calls them. As long as deCODE and Iceland provide bullet-proof protection against misuse, deCODE and Iceland maintain that the Act adequately protects patients. With a secure database, patients would receive the benefits of an accurate, individualized health database that could instantly be used in emergency situations, while simultaneously the patient would be assured complete privacy.¹⁵⁰ In sum, Stefansson (and Iceland) remain “convinced that most people in this world are willing to make sacrifices when it comes to our medical privacy to make sure that we can advance medicine for our children and grandchildren.”¹⁵¹
47. The database presents a deeper concern, however, which deCODE and the Alþingi have failed to address: self-autonomy. Combining the health records database with deCODE's genealogical and genetic resources makes the health database scarily powerful, some critics conclude.¹⁵² According to this analysis, the sheer scope of the project catapults the health database into an area where the doctor-patient confidentiality relationships are at stake and the basic wishes of a person should be respected.
48. The self-autonomy analysis presents a compelling argument that continues to feed the deCODE controversy. Medical histories, which document physical, mental, social, and dietary dysfunctions, contain an astonishing degree of knowledge about an individual. Our intimate relationships weave themselves into the records when we test ourselves for disease, handle a pregnancy, or reveal the bruises left by our batterers. Our internal

¹⁴³ See George J. Annas, *Rules for Research on Human Genetic Variation—Lessons from Iceland*, 342 NEW ENG. J. MED. 1830, 1833 (2000) (expressing ethical concerns about the research setting).

¹⁴⁴ Most notable is that of Mannvernd, discussed *infra*, at <http://www.mannvernd.is/english/> (last visited Apr. 4, 2002).

¹⁴⁵ Many thanks to David Winickoff, who contributed his insight about the bioethical debate from his unique perspective as a former intern at Mannvernd.

¹⁴⁶ See *Health Database Bill*, *supra* note 68, at Notes to Bill.

¹⁴⁷ See, e.g., Woodard, *Tempest in Iceland's Gene Pool*, CHRISTIAN SCI. MONITOR, June 30, 2000, at 6.

¹⁴⁸ See Melvin G. McInnis, *The Assent of a Nation: Genethics and Iceland*, 55 CLINICAL GENETICS 234–39 (1999).

¹⁴⁹ *POPULATION, INC.*, *supra* note 16, at 50.

¹⁵⁰ *Id.* In his support of this position, Stefansson rightly points out that most health record information is accessed through a presumed consent model by research facilities. As Stefansson argues, “there's not a single place in the world where people use information produced in the process of delivering health care with anything except presumed consent.” *Id.*

¹⁵¹ Woodard, *supra* note 147, at 6.

¹⁵² Woodard, *supra* note 29, at A6; Marshall, *supra* note 29, at 53.

frustrations also appear in our health records, when such stress increases our blood pressure or leads our doctor to up our Prozac. In a connected database, the already cloyingly intimate knowledge about a patient's past that is in his medical records can be compounded with the genetic sins of the patient's family and their own medical histories.¹⁵³ If a patient chooses to hand over a specimen to deCODE directly, he then goes one step further and allows deCODE to know his physical future.¹⁵⁴ The megadatabase may answer the questions of whether a person will "fall dead of heart attack in [his] 50s or fade slowly away with heart failure in [his] 90s? Will breast cancer or Alzheimer's be [his] fate? Schizophrenia or depression? Diabetes?"¹⁵⁵ Even in the most protected benevolent world, where one could insure that no one would ever know the real "us," an argument exists that a private sphere of autonomy connects to the megadatabase and its implications. The question critics then ask is: Do we even want to know ourselves what the database would reveal?¹⁵⁶ In this respect, deCODE cannot adequately address concerns with any fortification measure; only an opt-in provision would satisfy the deeper questions about self-direction, according to opponents of the Health Database Act.

b. Database Construction Stymied

49. The controversy surrounding the health database has created a host of problems for deCODE. The health database continues to remain under construction and has not yet reached its full potential because of actions taken by critics intent on vindicating patient rights.¹⁵⁷ Ethicists, doctors, and the Icelandic public all have slowed the health records database.
50. One of the largest opponents of the Health Database Act continues to be Mannvernd (the Association of Icelanders for Ethical Science), an organization formed with the sole intent of defeating the legislation.¹⁵⁸ Mannvernd echoes the general concerns about privacy and doctor-patient confidentiality while also attacking deCODE's de facto monopoly on the database.¹⁵⁹ Mannvernd filed a complaint against the constitutionality of the Act, alleging violations of human rights standards based on the presumed consent standard.¹⁶⁰ The case still pends, but a win would dismantle an entire branch of deCODE's business strategy. Should the case fail, Mannvernd may instead choose to target deCODE for litigation; the group has threatened deCODE with a lawsuit in the past and may at any time place deCODE in its crosshairs.¹⁶¹
51. Dissent from the Act does not end with Mannvernd or the direct attacks in the press. The Icelandic Medical Association (IMA) opposed the Health Database Act and called upon

¹⁵³ See Woodard, *supra* note 29, at A6.

¹⁵⁴ *Id.*

¹⁵⁵ Gary Taubes, *Your Genetic Destiny for Sale*, TECH. REV. (Cambridge, MA), Apr. 1, 2001, at 41.

¹⁵⁶ *See id.*

¹⁵⁷ deCODE 10Q, *supra* note 18, at 23-24.

¹⁵⁸ Abi Berger, *Private Company Wins Rights to Icelandic Gene Database*, 318 BRIT. MED. J. 11 (Jan. 2, 1999).

¹⁵⁹ *Id.*

¹⁶⁰ deCODE 10Q, *supra* note 18, at 24; *see POPULATION, INC.*, *supra* note 16, at 50; Taubes, *supra* note 155, at 41.

¹⁶¹ deCODE 10Q, *supra* note 18, at 24.

its doctor members to not relinquish patient records.¹⁶² The recalcitrance of doctors and institutional managers hampers the development of the health database, as many health care providers agree with the IMA's stance and refuse to negotiate with deCODE for the release of records. As to date, only 19 health institutions in the country of Iceland have contracted with deCODE to turn over medical data.¹⁶³ Because the Act does not mandate access to the health records, the indirect resistance of doctors adds drag to the completion of the database.¹⁶⁴ According to reports, one-third of Icelandic doctors refuse to hand over patient files, citing the need for patient-client confidentiality and the protection of patient autonomy.¹⁶⁵ One psychiatrist eloquently explained his concerns about the Health Database Act: "Patients come and talk to me, and at night I'm supposed to send the information to a third party that can sell it on the world market.... That is extremely troublesome."¹⁶⁶ Like many doctors, Gudmundur Bjornsson, former head of the Icelandic Medical Association, expressed anger at deCODE over the presumed consent provisions, stating that "[n]obody was asked if they want their health information released because the law says you don't have to.... We offered to help deCODE obtain the informed consent of every Icelander alive, but they said no."¹⁶⁷ With doctors avoiding the bargaining table, deCODE faces a significant hurdle in creating a national health database which can aid its research aims.

52. In addition to doctor recalcitrance and ethical pressures, the increasing number of opt-outs affects the ability of the health database to get off the ground. Approximately 7% of the Icelandic population has chosen to opt out of the database, removing 20,200 patients from the system as of September 30, 2001.¹⁶⁸ Because diseases can be rare, it is possible that at least some of the people who opt out are taking valuable genetic mutations along with them.¹⁶⁹ Opting-out also has become easier to do under a new bioethical agreement deCODE has signed with the IMA after years of haggling.¹⁷⁰ In an effort to appease the IMA's concerns about privacy and the presumed consent provisions, deCODE recently guaranteed that it would remove Icelanders who wish to opt out of the database immediately and purge records relating to that individual without any delay.¹⁷¹ The database will also be governed by ethical guidelines issued by the World Medical Association, giving an outside body substantial influence over the health records database.¹⁷²

53. The Health Database Act produced several negative effects on deCODE, which make the

¹⁶² See Berger, *supra* note 158, at 11.

¹⁶³ deCODE 10Q, *supra* note 18, at 23.

¹⁶⁴ *Id.* deCODE warns stockholders that "[w]e cannot be certain that we will enter into agreements with enough additional health institutions or on terms favorable to us." *Id.*

¹⁶⁵ Woodard, *supra* note 29, at A6.

¹⁶⁶ Enserink, *supra* note 136, at 890.

¹⁶⁷ Woodard, *supra* note 29, at A6.

¹⁶⁸ deCODE 10Q, *supra* note 18, at 21; Mannvernd, *Home Page*, at <http://www.mannvernd.is/english>.

¹⁶⁹ *Id.*

¹⁷⁰ See *Iceland: Groups Agree on Genetic Database Guidelines*, AM. HEALTH LINE, Sept. 4, 2001, at Research Notes; Press Release, deCODE genetics, Inc., Update on deCODE's Discussions with the Icelandic Medical Association, at <http://www.decode.com/news/releases/older/item.ehtm?id=3623> (Aug. 11, 2000).

¹⁷¹ *Iceland: Groups Agree on Genetic Database Guidelines*, *supra* note 170, at Research Notes.

¹⁷² *Id.*

database less attractive than planned. The media fascination with the opt-out provision and the Act's concept generated harsh criticism of the company that still continues. Among the strongest critics, Mannvernd plots to overturn the Act on constitutional grounds, while simultaneously threatening to sue deCODE directly. Moreover, doctors have sabotaged the plan indirectly by refusing to negotiate with deCODE over patient record collections. Individual opt-outs further reduce the potential scope of the database. The result of these external pressures is the contraction of the health database and its potential, with the database remaining incomplete and immature several years after the Act's passage.

2. deCODE's Scientific Accomplishments

54. Despite the fact that the health records database remains underdeveloped, criticized, and underutilized,¹⁷³ deCODE has made significant headway in isolating the genes that may be involved in some of the most common diseases in the world. The company has published more than thirty times in scientific journals, detailing its discoveries and observations from examining the blood of the Icelandic people.¹⁷⁴
55. The first hint of scientific success for deCODE came shortly after the company began operations, but years before the passage of the Health Database Act. In 1997, the company announced that it had "localized" a gene responsible for familial essential tremor (FET).¹⁷⁵ More common than Parkinson's disease, essential tremor is characterized by extremely shaky hands and arms. Affecting mainly the elderly, the disease affects the ability of the patient to accomplish even simple physical tasks. In the FET research, the company identified which chromosome contained the faulty gene, tracing the disease to chromosome 3.¹⁷⁶ The researchers did not isolate the disease gene itself, however. Though deCODE admittedly accomplished only the first step in isolating the genetic cause of the disease, the remarkable speed of its research was emphasized in the press. The localization took only three months instead of the expected six months had the research been attempted on a heterogeneous population.¹⁷⁷
56. Shortly after its success with FET, deCODE researchers began discovering loci linked to common diseases rather than simply identifying the responsible chromosome. A more impressive scientific feat, the discoveries were published extensively in scientific trade journals for genetics and genomics research. The first "loci" discovery involved the disease of osteoarthritis, a very common joint disease that can require hip and knee

¹⁷³ deCODE 10Q, *supra* note 18, at 20-24.

¹⁷⁴ deCODE genetics, Inc., *Resources: Scientific Papers*, at <http://www.decode.com/resources/papers/> (last visited Sept. 20, 2002).

¹⁷⁵ Press Release, deCODE genetics, Inc., Icelandic Genomics Company Identifies Location of Gene for Essential Tremor at <http://www.decode.com/news/releases/older/item.ehtm?id=1562> (Aug. 25, 1997). Multiple news sources reported on the discovery. *See, e.g.*, Clive Cookson, *Tremor Gene Tracked Down*, FIN. TIMES (London), Aug. 28, 1997, at 24; Matthews, *supra* note 123, at 20; *Viking legacy: a small, isolated country, Valhalla for gene hunters*, BIOTECH. NEWSWATCH, Sept. 15, 1997, at 1.

¹⁷⁶ Gulcher, et al., *Mapping of a Familial Essential Tremor Gene, FET1, to Chromosome 3q13*, 17 NATURE GENETICS 84, 85-86 (1997).

¹⁷⁷ *E.g.*, Cookson, *supra* note 175, at 24; Matthews, *supra* note 123, at 20.

replacements.¹⁷⁸ Other “loci” discoveries soon followed. A published study on pre-eclampsia revealed that deCODE had yet again found an area of the chromosome that appears responsible for the condition.¹⁷⁹ Pre-eclampsia is characterized by dangerously elevated blood pressure and excessive swelling in pregnant women, and may lead to the death of the mother or child.¹⁸⁰ Other diseases successfully targeted to a specific loci by deCODE include: Alzheimer’s;¹⁸¹ osteoporosis;¹⁸² rheumatoid arthritis;¹⁸³ Type 2 diabetes;¹⁸⁴ Parkinson’s disease;¹⁸⁵ and even obesity¹⁸⁶ and anxiety.¹⁸⁷

57. deCODE has also made significant achievements in finding the actual gene responsible for a disease. From their press releases, the company claims to have found the first genes ever discovered to be linked to schizophrenia,¹⁸⁸ common stroke,¹⁸⁹ and peripheral arterial occlusive disease (PAOD), a condition analogous to cardiovascular disease that involves the narrowing of the arteries in the arms and legs.¹⁹⁰ deCODE’s discoveries for the genes for stroke and PAOD were even published in a peer-reviewed American scientific journal in February 2002.¹⁹¹ Overall, deCODE claims to have discovered 20

¹⁷⁸ Press Release, deCODE genetics, Inc., deCODE genetics and Roche Announce Progress in Osteoarthritis Research Program at <http://www.decode.com/news/releases/older/item.ehtm?id=1425> (Mar. 26, 1999).

¹⁷⁹ Arngrímsson, et al., *A Genome-Wide Scan Reveals a Maternal Susceptibility Locus for Pre-Eclampsia on Chromosome 2p13*, 8 HUMAN MOLECULAR GENETICS 1799, 1799 (1999); Press Release, deCODE genetics, Inc., deCODE genetics Maps a Gene Linked to Pre-eclampsia at <http://www.decode.com/news/releases/older/item.ehtm?id=1429> (Sept. 20, 1999) [hereinafter Pre-eclampsia Press Release]; *Gene Discovery, Cardiovascular Disease, deCODE genetics: deCODE genetics Identify Locus Linked to Pre-eclampsia*, R&D FOCUS DRUG NEWS, Sept. 27, 1999.

¹⁸⁰ Pre-eclampsia Press Release, *supra* note 179.

¹⁸¹ Press Release, deCODE genetics, Inc., deCODE and Roche Announce Milestone in Alzheimer’s Research at <http://www.decode.com/news/releases/older/item.ehtm?id=3626> (Aug. 18, 2000); *Gene Discovery, CNS disease, deCODE genetics, Roche Map Gene for Stroke*, R&D FOCUS DRUG NEWS, Apr. 20, 2000.

¹⁸² Osteoporosis Press Release, *supra* note 56.

¹⁸³ Press Release, deCODE genetics, Inc., deCODE and Roche Announce Mapping of Gene Linked to Rheumatoid Arthritis at <http://www.decode.com/news/releases/older/item.ehtm?id=21002> (Nov. 29, 2001).

¹⁸⁴ Press Release, deCODE genetics, Inc., deCODE and Roche Announce Identification of Stroke Gene and Location of Gene Linked to Type 2 Diabetes at <http://www.decode.com/news/releases/older/item.ehtm?id=13782> (May 22, 2001).

¹⁸⁵ Press Release, deCODE genetics, Inc., deCODE Locates First Gene Linked to Late-onset Parkinson’s Disease (Oct. 23, 2001) at <http://www.decode.com/news/releases/older/item.ehtm?id=19601> (Oct. 23, 2001). Other scientists previously isolated the gene for rarer forms of Parkinson’s disease. *Id.*

¹⁸⁶ Press Release, deCODE genetics, Inc., deCODE and Roche Announce the Location of Genes Linked to Obesity and Anxiety at <http://www.decode.com/news/releases/older/item.ehtm?id=18281> (Sept. 11, 2001).

¹⁸⁷ *Id.*

¹⁸⁸ Press Release, deCODE genetics, Inc., deCODE genetics and Roche Announce Identification of Schizophrenia Gene at <http://www.decode.com/news/releases/older/item.ehtm?id=4303> (Oct. 20, 2000).

¹⁸⁹ S. Gretarsdottir, et al., *Localization of a Susceptibility Gene for Common Forms of Stroke to 5q12*, 70 AM. J. HUMAN GENETICS 593 (2002); Press Release, deCODE genetics, Inc., Scientists at deCODE genetics Map Stroke Gene at <http://www.decode.com/news/releases/older/item.ehtm?id=1461> (Mar. 29, 2000).

¹⁹⁰ G. Gudmundsson, et al., *Localization of a Gene for Peripheral Arterial Occlusive Disease to Chromosome 1p31*, 70 AM. J. HUMAN GENETICS 586 (2002); Press Release, deCODE genetics, Inc., deCODE and Roche Announce Major Progress in Turning their Genomic Discoveries in Schizophrenia and PAOD into Novel Drugs and Diagnostics at <http://www.decode.com/news/releases/older/item.ehtm?id=7462> (Feb. 14, 2001). Only a few months earlier, deCODE announced they had found a larger locus for the gene, but not the gene itself. Press Release, deCODE genetics, Inc., deCODE genetics and Roche Map Risk Factor for Arterial Disease of the Legs and Arms at <http://www.decode.com/news/releases/older/item.ehtm?id=5086> (Nov. 14, 2000).

¹⁹¹ Gretarsdottir, et al., *supra* note 189, at 593.

specific genes that may cause disease, and is working on ten potential drug targets for patients with such mutations.¹⁹²

58. As discussed in Section II, genetic discoveries, while valuable scientifically, are only one step toward a successful and profitable biotechnology business. The prospect of drug therapies and diagnostics recently has become a driving motivation for deCODE. Though market analysts initially reported that deCODE would earn profits mainly through licensing its databases and mining tools,¹⁹³ the more recent business activities and statements by Stefansson suggest otherwise. The company announced it had embarked on a “downstream development program,” which aims to produce marketable therapies and diagnostics based on the genetic discoveries it has already made.¹⁹⁴ To protect its drug discovery opportunities, deCODE recently went on a patent application spree. In November 2001, the company announced it had filed 350 patent applications on possible drug targets.¹⁹⁵ In addition, deCODE has developed partnerships and alliances among biotechnology and pharmaceutical companies to aid in its drug development mission.

3. deCODE’s Business Developments

59. While deCODE has yet to turn a financial profit, it has formed a web of lucrative arrangements that provide cash flow and complementary research capabilities to the young firm. Since its incorporation, the company has also completed a successful initial public offering, weathered the decline in the NASDAQ, and accomplished a merger with another biotechnology company. The business developments of the firm bear scrutiny, given that Iceland will never receive more than \$1.4 million a year from the use of its people’s health information.¹⁹⁶ This section highlights the financial progress of deCODE.
60. Following an industry trend, deCODE continues to establish alliances among business competitors and pharmaceutical companies.¹⁹⁷ The partnerships and acquisitions entered into by deCODE reveal the presence of a strategic plan that involves diversifying their research capabilities, developing all possible products from their databases, and otherwise capitalizing upon their unique assets to the greatest extent possible.
61. The most notable partner of deCODE is Roche, also known as Hoffmann-La Roche, an established and renowned pharmaceutical company with worldwide offices employing over 60,000 people.¹⁹⁸ Since 1998, the Swiss company has entered into three agreements

¹⁹² deCODE, *Company Milestones*, *supra* note 6.

¹⁹³ *Rapid Growth Pushes deCODE Towards Flotation*, PHARM. BUS. NEWS, May 11, 1998 (asserting that “deCODE does not intend to become a diagnostics or pharmaceutical company” but will instead be “developing subscription revenues from its unique database”).

¹⁹⁴ Press Release, deCODE genetics, Inc., deCODE Files Patents on 350 Drug Targets—All with Population Linkage Data in Major Diseases at <http://www.decode.com/news/releases/item.ahm?id=20141> (Nov. 7, 2001).

¹⁹⁵ *Id.*

¹⁹⁶ *See infra* Section II.C.2.

¹⁹⁷ Marion Webb, *Bio Meeting Spawns Hopes Of Ventures; The Impact of Biotechnology Conference BIO 2001*, SAN DIEGO BUS. J., July 9, 2001, at 1.

¹⁹⁸ Clive Cookson, *Roche in Iceland Research*, FIN. TIMES (London), Feb. 3, 1998, at 27; Hoffman –La Roche, *Our Global Presence, Introduction and Key Note*, at http://www.roche.com/home/company/com_glob_intro.htm (last visited Apr. 4, 2002).

with deCODE to provide milestone payments to deCODE for scientific achievements. The first contract, which was valued at over \$200 million, provided for equity investment in deCODE and milestone payments for research developments until 2003.¹⁹⁹ In exchange for the payments, deCODE launched into research on twelve diseases, roughly grouped into categories of cardiovascular, psychiatric, and metabolic disorders.²⁰⁰ After collecting \$135 million from Roche under the first agreement,²⁰¹ deCODE signed another deal with Roche that continues the 1998 collaboration.²⁰² The new three-year alliance signed in 2002 ties the companies until 2005, and increases the value of the relationship according to market analysts. Under the continuance, deCODE will focus on developing treatments for four diseases and will have more of role in the stage of drug design and clinical trial work.²⁰³ Under both the 1998 and 2002 agreements, Roche agreed to provide Icelanders with any medicine that is developed,²⁰⁴ a gesture some denounce as “throwing glass beads to the natives,”²⁰⁵ but nevertheless adds value to Icelanders.

62. The third multi-million dollar contract with Roche focuses less on scientific milestones and more on developing commercial products such as diagnostic tests.²⁰⁶ Valued at \$50 million, the diagnostics deal contemplates bringing diagnostic tests and products to market starting in 2003.²⁰⁷ Under the terms of the agreement, deCODE will receive “double-digit” royalties from any sales that occur.²⁰⁸
63. In addition to its partnerships with Roche, deCODE has allied itself with other key biotechnology players. The relationships complement deCODE’s goals of gene discovery and drug development by providing needed technologies to the company. For its software and lab equipment needs, deCODE has locked itself into a contract with Applied Biosystems Group, a Silicon Valley firm that excels in the development of such tools.²⁰⁹ Affymetrix developed an early contract with deCODE to aid in gene technology as well.²¹⁰ On the pharmaceutical development side, deCODE recently entered into a highly publicized arrangement with Pharmacia, a well-respected American pharmaceutical

¹⁹⁹ *Roche to Pay deCODE*, *supra* note 39.

²⁰⁰ Cookson, *supra* note 198, at 27.

²⁰¹ Kim Coghill, *deCODE, Roche Sign New Deal for Compound Development*, BIOWORLD TODAY, Jan. 30, 2002.

²⁰² Kim Frick, *Roche, deCODE Agree to New Three-Year Drug Alliance*, BLOOMBERG NEWS, Jan. 29, 2002, available at LEXIS, News Library, News Group File, All; Press Release, deCODE genetics, Inc., deCODE and Roche Unveil New Alliance in Drug Discovery and Development at <http://www.decode.com/news/releases/item.ehtm?id=22962> (Jan. 29, 2002).

²⁰³ MORGAN STANLEY, DECODE GENETICS COMPANY UPDATE: ROCHE EXTENSION PROVIDES MORE LONG-TERM VALUE 2 (2002).

²⁰⁴ *Roche to Pay deCODE*, *supra* note 39.

²⁰⁵ See Matthew Willett, *deCODE, Roche Make Advances, Move Work Into Discovery Phase*, BIOWORLDTODAY, Feb. 15, 2001.

²⁰⁶ Kim Coghill, *supra* note 126.

²⁰⁷ *Id.*

²⁰⁸ *Id.*

²⁰⁹ *Genotyping Analysis Alliance Begun; Applied Biosystems Group and deCODE genetics Inc. Work to Create Genotyping Software*, DRUG DISCOVERY & TECH. NEWS, Aug. 1, 2001. The contract lasts for three years.

²¹⁰ *DeCODE’s in Chip Deal with Affymetrix*, BIOTECH. NEWSWATCH, June 7, 1999, at 2.

company.²¹¹ The agreement calls for deCODE to develop tests to determine which patients would most benefit from Pharmacia's newest medicines.²¹² In addition to the collaboration with Pharmacia, deCODE will also attempt to design its own drug products. The goal of drug development led deCODE to purchase MediChem Life Sciences, which has a large research staff of chemists and extensive drug design experience.²¹³ The acquisition closed March 18, 2002.²¹⁴ The variety of partners that deCODE has aligned itself with adds a range of abilities to the company that sets the company up for long-term survival and financial success.

64. Financing for deCODE does contain a large amount of risk, however. In the summer of 2000, deCODE chose to go public by launching an initial public offering. While the IPO generated over \$172 million in capital, the move also made deCODE much more susceptible to the whimsy of investors.²¹⁵ deCODE got in on the tail end of the technology bubble and its IPO share price of \$18 rose to a high of over \$30 per share.²¹⁶ Like other technology stocks, however, the decline of the bioinformatics market has impacted deCODE's shares dramatically;²¹⁷ the stock price entered a freefall and bottomed out at slightly more than \$5 per share.²¹⁸ With "virtually every Icelander" having a financial stake in the company through their pensions, individual investments, or through local government investments,²¹⁹ the drop of deCODE's stock price caused Icelanders to verbally attack Stefansson and deCODE.²²⁰ The company also now faces a class action securities lawsuit, a common occurrence when market prices sour.²²¹
65. Luckily for deCODE, the stock price has slowly recovered and moved upward. Recent reports rank deCODE as number 15 among the top 50 biotechnology companies in Europe,²²² and the company's revenues place it in the top 30 in the world among drug discovery firms.²²³ The company is valued somewhere around \$600 million.²²⁴ However,

²¹¹ MORGAN STANLEY, DECODE GENETICS COMPANY UPDATE: PHARMACIA COLLABORATION SETS THE BALL ROLLING 1-2 (2002); David Firm, *Pharmacia in Genes Project with deCODE*, FIN. TIMES (London), Jan. 16, 2002, at 28.

²¹² MORGAN STANLEY, *supra* note 211, at 2.

²¹³ *Iceland's deCODE to acquire MediChem Life Sciences for \$83.6 million*, MARKETLETTER, Jan. 14, 2002.

²¹⁴ Press Release, deCODE genetics, Inc., deCODE Announces Completion of MediChem Acquisition at <http://www.decode.com/news/releases/item.ehtm?id=25325> (Mar. 18, 2002).

²¹⁵ Karen Pihl-Carey, *deCODE, Transgenomic IPOs Raise \$240M in Revived Market*, BIOWORLD TODAY, July 19, 2000.

²¹⁶ *Id.*; *Stroke Gene Identified: deCODE Genetics, Inc.*, GENOMIKA, May 23, 2001, at 2.

²¹⁷ Rana Foroohar, *The Gene Bubble*, NEWSWEEK, Feb. 18, 2002, at 42.

²¹⁸ Market statistics for deCODE can be found on NASDAQ's website, <http://www.nasdaq.com/>. The ticker for deCODE is DCGN. Information about high and low share prices within a year's period can be accessed by selecting the link entitled "Fundamentals."

²¹⁹ Crenson, *supra* note 29, at 6; *see Iceland: Critics Question Value of deCODE Gene Studies*, AM. HEALTH LINE, Mar. 26, 2001, at Research Notes.

²²⁰ *See* Borchert, *supra* note 8.

²²¹ *Milberg Weiss Announces Class Action Suit Against deCODE Genetics, Inc. and Certain Underwriters of its Initial Public Offering*, BUS. WIRE, Dec. 7, 2001.

²²² *Stock tables; Top 50 biotechnology and pharmaceutical company investment information*, BIOVENTURE VIEW, Nov. 13, 2001, at 7. The company ranks 15th in this report.

²²³ *Bioinformatics in the Forefront: Software and Databases are in Ample Supply and in Great Demand as Pharmaceutical Companies are Eager to Identify New Drug Targets*, MED AD NEWS, Nov. 1, 2001, at 42 [hereinafter *Bioinformatics in the Forefront*].

the market position at deCODE is far from secure. Some analysts continue to rate the stock a “strong buy” based on its research so far and its rosy future,²²⁵ but many analysts press the company to “deliver” to the market.²²⁶ These latter analysts have adopted a wait and see attitude toward deCODE, refusing to recommend the company for purchase until the company can develop products.²²⁷ To meet these demands, deCODE plans to sell subscriptions to its database by the end of 2002,²²⁸ as well as continue its long range plans for development with Pharmacia, Roche, and the newly acquired MediChem Life Sciences.

66. In 2002, deCODE enjoys a somewhat enviable position among biotechnology firms, despite its earlier mishaps in the stock market. An impressive line-up of suppliers and collaborating partners provides the company with many benefits. deCODE’s contracts are worth hundreds of millions of dollars, and royalty fees for products will only increase such revenue. Other strategic relationships increase deCODE’s research capabilities far beyond the area of genomics and allow the company to venture into drug development. Finally, the business activity of deCODE has led to significant confidence in the company by sophisticated marketwatchers, who anticipate bountiful riches from products created through deCODE’s approach to genetics. The company’s high market valuation and integration with pharmaceutical and biotechnology interests suggests staying power for the company, and perhaps the industry as a whole.

B. Present Condition of Iceland

67. Iceland has also benefited from its arrangement with deCODE. According to the legislative history accompanying the Health Database Bill, the Alþingi contemplated that construction of a centralized database would not only boost health care quality, but would provide economic and informational advantages to the island. An enterprising nation, Iceland intended to “sail its national ship into the genetic future” and capitalize on the unique provisions of the Health Database Act.²²⁹ As noted by the Alþingi:

The benefits of the database may be divided into four main categories: 1) acquisition of new knowledge on health or disease, 2) improved quality and economy in the health system, 3) development of high-technology industry in Iceland, and thus employment for a highly educated sector of society, 4) potential for attracting to Iceland business relating to the database.²³⁰

68. Even with the stagnation of the health database that currently exists, the very presence of deCODE in Iceland acts to further the goals outlined in the Act. The island has received a

²²⁴ Bradley, *supra* note 142.

²²⁵ LEHMAN BROTHERS, DECODE GENETICS COMPANY UPDATE: DRUG DISCOVERY COLLABORATION WITH ROCHE 2 (2002).

²²⁶ MORGAN STANLEY, *supra* note 211, at 3.

²²⁷ MORGAN STANLEY, *supra* note 211, at 1, 3. ROBERTSON STEVENS, DECODE GENETICS, INC. ENTERS INTO HEART DISEASE PHARMACOGENETICS ALLIANCE WITH PHARMACIA 3 (2002).

²²⁸ MORGAN STANLEY, *supra* note 211, at 3; Frick, *supra* note 16.

²²⁹ Jonatansson, *supra* note 13, at 65-66.

²³⁰ *Health Database Bill*, *supra* note 68, Notes to Bill.

variety of benefits from hosting the young start-up, though many benefits remain ephemeral and depend on deCODE's continuing success.

1. Improvements in Knowledge and Health

69. The scientific strides deCODE has made over the last few years directly impact the goal of gaining knowledge about health and disease, the first mentioned goal of the Health Database Act. Because deCODE's discoveries are based on the genetic mutations of Icelandic people, uncovering mutations for many of the common diseases of Iceland provides basic knowledge about Icelanders that did not previously exist. As discussed earlier in this Section, deCODE has found specific genes linked to stroke, arterial disease, and schizophrenia, all of which are common diseases affecting thousands in Iceland alone.²³¹ The knowledge acquired is also specific to Icelanders; deCODE has not yet proven that such mutations are common to other people outside Iceland so the company has to date directly promoted knowledge only about the Icelandic people.²³² From the scientific discoveries generated by deCODE, doctors and other researchers have a foundation for developing possible drug treatments, gene therapies, diagnostics, preventative care strategies, and other methods for lessening the impact of the disease on Iceland.
70. Knowledge, however, provides only theoretical benefits—Iceland has not yet attained their second goal of improving the quality or the economics of their healthcare system through their collaboration with deCODE. A concrete benefit to Iceland will result if medicinal and diagnostic products emerge from the research conducted by deCODE, or if deCODE finally creates a working and doctor-accessible health database that can deliver complex information about patients to improve their health care.²³³
71. Because press releases suggest that deCODE is making progress toward developing drug products, Iceland may soon receive a free therapy under deCODE's promise from Roche.²³⁴ The Icelandic health care system currently strains to provide quality care with prices rising every year. Iceland currently devotes almost a fourth of its revenue to health care costs, a proportion that has increased over time.²³⁵ Alleviating payment for a drug

²³¹ See *supra* notes 188-190 and accompanying text.

²³² deCODE 10Q, *supra* note 18, at 22; Lawton, *supra* note 24, at 715.

²³³ In one of his press interviews, Stefansson gives an example of how the megadatabase of genetic, genealogical, and health records would aid patient care:

A colleague of mine, his car hit a tree a couple of years ago and he was seriously wounded, he almost died. When he was brought into the hospital, after he had been peeled out of his car, the hospital knew nothing about him except his name. Imagine if they would simply have been able to put his name into a centralized database and get all the health information there was on him, his parents, his siblings. The power of this is enormous...."

POPULATION, INC., *supra* note 16, at 50.

²³⁴ See *supra* notes 206-214 and accompanying text.

²³⁵ MINISTRY OF FIN., ICELAND, TREASURY FINANCES IN FEBRUARY 2002, at 2, at [http://government.is/interpro/fjr/fjr.nsf/Files/trfin022002/\\$file/trfin022002.pdf](http://government.is/interpro/fjr/fjr.nsf/Files/trfin022002/$file/trfin022002.pdf) (Mar. 2002). In both 2000 and 2001, the proportion of the budget spent on health care was only slightly over 20% and had remained steady. The figures for 2002 reveal that health care costs are now over 24% of the expenditures of the country.

treatment may substantially affect the country's budget. The probable value of free medicines can be found by considering the likelihood that such a drug will truly emerge and the corresponding benefit that Iceland would receive should the drug be developed. Given that some of these diseases can affect 1% or more of the population, thousands of Icelanders could receive free medicines should a product develop, saving the country millions. As an example, suppose that deCODE develops a new treatment for schizophrenia. Schizophrenia afflicts up to 1% of a population, so approximately 2850 Icelanders may benefit if a new drug is developed.²³⁶ A recent innovative treatment for this disease uses a drug called Ziprasidone,²³⁷ which costs \$8.12 a day for the average patient.²³⁸ Other patented anti-psychotic drugs for schizophrenia cost approximately the same amount, with prices typically ranging from \$7.75 to \$10.45 per day.²³⁹ If the drug developed by deCODE can fetch the same market price of around \$8 per day, each Icelander using the medicine would require \$2920 worth of medicine per year. Free medicines would thus save Icelanders or the Icelandic government up to \$8.3 million if every schizophrenic took the new medication.²⁴⁰ Such an example shows the potential upswing available to Iceland should such a drug ever become available.

72. As an additional benefit, successful treatment of a disease has positive spillover effects in Iceland. Because Iceland has one of the most extensive social welfare systems in the world,²⁴¹ a sick person may be relying on the government for a variety of services, not just their health care costs.²⁴² With successful treatments, patients may spend less time in the hospitals, miss fewer days of work, and perhaps lessen their need for government subsidies as they regain their health and are more capable of regaining a normal life.
73. There exists a very real probability that a drug product will not materialize, however, since approximately 75% of research funds in drug development go to failed projects.²⁴³ Because deCODE has yet to deliver any product, future benefits to Iceland remain to be seen.

²³⁶ *Icelandic Study Reveals Schizophrenia Gene*, CHEM. & INDUS., Nov. 6, 2000, at 698.

²³⁷ Letter from the Department of Health and Human Services, Food & Drug Administration, to Pfizer Central Research (Feb. 5, 2001), at http://www.fda.gov/cder/foi/nda/2001/20-825_Geodan_Approv.pdf (last visited Sept. 18, 2002).

²³⁸ Sirada Maphanta, *Pharmacotherapy Perspectives: Ziprasidone*, J. PHARM. SOC WISC. (Sept./Oct. 2001) at 27, available at <http://www.pswi.org/communications/PDFs/ziprasidone.pdf> (last visited Dec. 5, 2002). For purposes of this example, the average cost of Clozapine was excluded because it costs over \$31 per daily dose. Generally, these prices are for the United States, but that should not substantially affect the analysis. The example in the text gives the value of what deCODE and Roche forego by their promise to Iceland. The companies could have otherwise sold the drugs that they must donate to United States customers.

²³⁹ *Id.*

²⁴⁰ Of course, not every schizophrenic would take the new drug.

²⁴¹ Sailer, *supra* note 40.

²⁴² See MINISTRY OF FIN., ICELAND, TREASURY FINANCES IN JANUARY-APRIL 2001, at 3, at [http://fjarmalaraduneyti.is/interpro/fjr/fjr.nsf/Files/trfin-may2001/\\$file/trfin-may2001.pdf](http://fjarmalaraduneyti.is/interpro/fjr/fjr.nsf/Files/trfin-may2001/$file/trfin-may2001.pdf) (May 23, 2001). Iceland has an extensive welfare program and provides funding for senior citizens, the disabled, the unemployed, and those taking parental leave. The country also contributes to hospitals and nursing homes.

²⁴³ *Bioinformatics in the Forefront*, *supra* note 223, at 42.

2. Increased Technical and Business Opportunities

74. Iceland's last two goals, as espoused by the Alþingi, involve expanding the high tech and database-related sector of the country, as well as increasing employment opportunities for Icelanders. Some success on this axis has already been accomplished in Iceland. On the employment side, the move to establish Iceland as a biotech friendly country has considerably helped the retention of Icelanders skilled in the sciences. Prior to deCODE's existence, scientists and technology specialists were leaving Iceland for training and jobs abroad because of the lack of opportunities in the country.²⁴⁴ As the largest company in Iceland,²⁴⁵ deCODE employs over 600 people,²⁴⁶ most of whom have college degrees²⁴⁷ and many of whom are native Icelanders.²⁴⁸ The company's management and board of directors are heavily composed of Icelanders as well. For example, two established Icelandic doctors, Helgi Valdimarsson and Gudmundur Thorgeirsson, sit on deCODE's scientific advisory board.²⁴⁹ Several members of the company's management team are also of Icelandic descent, with many having spent time in the United States or abroad before finally returning to Iceland to work for deCODE.²⁵⁰ Consider the vice-president of Informatics at deCODE, Hakon Gudbjartsson, as only one example of returning scientists. After getting his undergraduate degree in Iceland, Gudbjartsson traveled to the United States for his graduate school training and remained in Boston until he returned to Iceland to begin a position within deCODE.²⁵¹ Because of the attractive nature of deCODE's scientific research model, the company may be helping to reverse Iceland's brain drain.
75. Iceland's dependence on a fishing economy has also been slightly alleviated. While nearly half of the country still earns a living through fishing and agricultural activities,²⁵² deCODE has become one of the country's largest commercial employers.²⁵³ In addition to increasing job diversity and retaining scientific talent, the presence of deCODE appears to have helped the country significantly expand its technology sector. In

²⁴⁴ See, e.g., Enserink, *supra* note 5, at 13 (quoting a member of the Committee on Health in the Alþingi as saying that those trained abroad can now "come home" and work with deCODE); Ruth Chadwick, *The Icelandic database—do modern times need modern sagas?*, 319 BRIT. MED. J. 441, 441 (1999).

²⁴⁵ Justin Keay, *As Isolation Gives Way to Parties...A Tidy Gene Pool Pays Off Big*, BUS. WK., May 1, 2000, at 4.

²⁴⁶ Frick, *supra* note 16.

²⁴⁷ See deCODE genetics, Inc., *Company Careers*, at <http://www.decode.com/company/careers> (last visited Apr. 4, 2002).

²⁴⁸ Grose, *supra* note 12, at 42 (stating that, in 1997, 90% of the company's employees were Icelandic).

²⁴⁹ See deCODE genetics, Inc., *Company Management: Scientific Advisory Board*, at http://www.decode.com/company/management/sci_council (last visited Apr. 4, 2002).

²⁵⁰ While many of the managers have Icelandic surnames, it is impossible to tell their countries of origin from their biographies. At the same time, many have spent significant amounts of time working in Iceland. When those facts are combined, it is logical to conclude that several of the managers may be native Icelanders like Stefansson. See, e.g., deCODE genetics, Inc., *Company Management: Company Management Team*, at http://www.decode.com/company/management/?dep_id=3521 (last visited Apr. 4, 2002).

²⁵¹ See deCODE genetics, Inc., *Company Management: Hakon Gudbjartsson: Vice President, Informatics*, at http://www.decode.com/company/management/manager.ahm?emp_id=461&dep_id=3521 (last visited Apr. 4, 2002).

²⁵² See OECD ECONOMIC SURVEYS—ICELAND, *supra* note 11, at 101. The approximate number is 44%. This is down from 59% in 1980. See also Keay, *supra* note 245, at 4.

²⁵³ See Keay, *supra* note 245, at 4.

December 2000, the market value of deCODE accounted for 7% of the gross domestic product of Iceland.²⁵⁴ Economic statistics show a massive 15% increase in spending on research and development in Iceland, even though the overall amount of high tech funding has not significantly improved.²⁵⁵ The high tech sector is thus one of the fastest growing sectors of the Icelandic economy, thanks in part to the contributions of deCODE.²⁵⁶

76. The presence of deCODE also has resulted in the creation of another population genomics company named Urður, Verðandi, Skull (UVS).²⁵⁷ Intending to compete directly with deCODE in accessing the riches of Icelandic homogeneity, UVS began shortly after deCODE's incorporation.²⁵⁸ Part of Iceland Genomic Corporation, UVS opposed the Health Database Act and used only volunteered information in their studies.²⁵⁹ The small 35-person company works under contractual agreements with the nation's leading cancer institutes and is currently studying 17 varieties of cancers.²⁶⁰ While only a beginning, the presence of an additional biotechnology start-up helps further Iceland's goals of encouraging technology in the country.

IV. Lessons From the Icelandic Experiment

77. Because deCODE genetics was formed over five years ago, it has the dubious distinction of "launch[ing] a revolution in population genomics."²⁶¹ Since deCODE's creation in 1997, a number of private bioprospecting companies have elbowed into the field, with researchers combing homogenous populations in increasingly remote locations. To combat the possible invasive character of such entrepreneurs, governments and other intervening bodies have been interjecting themselves between the researchers and the target population, much in the manner that Iceland did through the Health Database Act. Some lessons from the Icelandic experience may inform these new regulatory interactions and be a benefit to both parties. The goal of this Section is to make three generalized observations about bioprospecting arrangements in light of what we have learned about deCODE from Sections II and Section III.

A. The Spread of Bioprospecting and its Regulation

78. A rash of bioprospecting companies have been formed recently to study a variety of diseases and populations. The list stretches into all corners of the world. Researchers currently study in Italy,²⁶² Sicily,²⁶³ Sardinia,²⁶⁴ Pingelap Island in the Western Pacific,²⁶⁵

²⁵⁴ See OECD ECONOMIC SURVEYS—ICELAND, *supra* note 11, at Biotechnology Services.

²⁵⁵ *See id.*

²⁵⁶ Keay, *supra* note 245, at 4.

²⁵⁷ Enserink, *supra* note 6, at 951.

²⁵⁸ *Id.*

²⁵⁹ *Id.*

²⁶⁰ See Icelandic Genomics Corporation, *Company Overview and History*, at <http://www.uvs.is/eng/about/company.html> (last visited Apr. 4, 2002); Icelandic Genomics Corporation, *National Hospital to Begin New Cancer Research*, NORDIC BUS. REP., Jan. 11, 2001.

²⁶¹ POPULATION, INC., *supra* note 16, at 50.

²⁶² Simon Bevilacqua, *Islands Become Havens of Research*, SUNDAY TASMANIAN, July 8, 2001.

Norfolk,²⁶⁶ Turkey,²⁶⁷ Ireland,²⁶⁸ Mongolia,²⁶⁹ Israel,²⁷⁰ Barbados,²⁷¹ Latvia,²⁷² Tonga,²⁷³ Estonia,²⁷⁴ Newfoundland,²⁷⁵ Sweden,²⁷⁶ and Quebec,²⁷⁷ among others. Specific populations in larger countries are also being targeted with the Mormons²⁷⁸ and Amish²⁷⁹ in the United States and certain ethnic enclaves in China²⁸⁰ proving to be interrelated enough for genomic studies. The scientists are looking for genetic links to a number of diseases, including Alzheimer's, asthma, cancer, hypertension, heart disease, depression and color blindness, to name but a few.²⁸¹

79. As the numbers of bioprospecting companies has grown, the response by the population under study has also changed. Early bioprospecting expeditions tended to adopt a more love 'em and leave 'em attitude toward their research subjects rather than forging a relationship with the country. Termed "helicopter genomics," early bioprospecting companies often engaged in "the practice of flying in and taking blood from the natives, before disappearing, to patent and profit from the data."²⁸² Based on a growing sense of exploitation, target populations have increasingly begun to protect themselves through the intervention of their officials and community leaders. In addition to Iceland's intervention, the Chinese government passed a bill preventing bioprospecting without the aid of a Chinese research group,²⁸³ and the Mongolian government also has negotiated with a bioprospecting company on behalf of its people.²⁸⁴ The government of Estonia has

²⁶³ *Id.*

²⁶⁴ *Id.*; *Italian Start-up to Begin Gene Research Project in Sardinia*, *supra* note 15, at 2.

²⁶⁵ Bevilacqua, *supra* note 262.

²⁶⁶ *Id.*

²⁶⁷ *Id.*

²⁶⁸ *HiberGen and SEQUENOM Establish Licensing Agreement for HiberGen's SNaPIT Technology in Mass Spectrometry*, PR NEWSWIRE, July 9, 2001 (discussing the Irish genomics company HiberGen).

²⁶⁹ *Drug-related Genome Research Focuses on Isolated Populations*, THE NIKKEI WEEKLY, July 2, 2001 (reporting on approval granted to study Mongolians).

²⁷⁰ Avi Machlis, *Gene-seekers Look for Big Clues in a Tiny Population*, FIN. TIMES (London), June 25, 2001, at 12 (noting research on Ashkenazi Jews in Israel).

²⁷¹ *Isolated Barbados Population Helps Researchers Zero In on Asthma and Allergic Disease Genes*, ASCRIBE NEWSWIRE, Feb. 5, 2001.

²⁷² *Latvian Population Genetics Company Formed*, GENOMIKA, July 18, 2001, at 2.

²⁷³ Tom Hollon, *Gene Pool Expeditions*, THE SCIENTIST, Feb. 19, 2001, at 1.

²⁷⁴ *Id.*

²⁷⁵ Taubes, *supra* note 155, at 41.

²⁷⁶ *Id.*

²⁷⁷ *Genetics Screening Projects Target Populations; Galileo Genomics*, GENOMIKA, Mar. 28, 2001, at 5.

²⁷⁸ Kimberly Blanton, *Corporate Takeover Exploiting the US Patent System*, THE BOSTON GLOBE, Feb. 24, 2002, at 10 (discussing Myriad Genetic's monopoly on testing for BRCA1 and BRCA2, two breast cancer genes found from studies of Mormon women.)

²⁷⁹ Hawkes, *supra* note 15, at A-8.

²⁸⁰ See John Pomfret & Deborah Nelson, *An Isolated Region's Genetic Mother Lode; Harvard-led Study Mined DNA Riches; Some Donors Say Promises Broken*, WASH. POST, Dec. 20, 2000, at A01 (reporting on genomic studies in remote farming villages in China).

²⁸¹ See Bevilacqua, *supra* note 262.

²⁸² *Rapid Growth Pushes deCODE Towards Flotation*, *supra* note 193.

²⁸³ See generally, THE MINISTRY OF SCI. & TECH. & THE MINISTRY OF PUB. HEALTH, PEOPLE'S REPUBLIC OF CHINA, INTERIM MEASURES FOR THE ADMIN. OF HUMAN GENETIC RESOURCES (June 10, 1998), at <http://www.usembassy-china.org.cn/sandt/generesourcesreg10-98.html> (last visited Apr. 6, 2002).

²⁸⁴ *Drug-related genome Research Focuses on Isolated Populations*, *supra* note 269.

gone far beyond intervention and instead owns the bioprospecting companies that mine populations in Estonia and nearby Tonga.²⁸⁵ Governments are not the only parties involved in bioprospecting regulation. The Medical Research Council in Britain is overseeing a 500,000-person bioprospecting mission, and a regional ethics council must approve the actions of UmanGenomics, a Swedish population company.²⁸⁶ Paralleling the growth of bioprospecting as a whole is the increased regulation of the industry through approval processes regulating access to the people under study.

B. Limitations on Comparing the deCODE-Iceland Agreement with Other Agreements

80. In shifting from helicopter genomics to a more regulated genetic excavation scheme, there exists the need to forge appropriate contracts between companies and those who control access to the population to be studied. Some remote populations will have no intervening authority that can protect the inhabitants from companies bent on exploitation without compensation. When an intervening body does come between researchers and their subjects, however, deCODE can be used as an example to extract greater wealth for the target population. In a similar vein, knowledge about deCODE and Iceland gives bioprospecting companies an idea of what policies to avoid in order to not bring unnecessary trouble into the relationship.
81. Even when regulation can occur, no company or its targets will be in exactly the same situation as deCODE and Iceland. A host of conditions may distinguish any given bioprospecting arrangement from that of deCODE's. The homogeneity of a population may make research more or less difficult, and the quality of genealogical records will also affect the research bargain. In addition, a country may be better or worse equipped to tether a bioprospecting company. The availability of research facilities, trained personnel, and appropriate infrastructure all will be important considerations to a community and the corporation targeting it. Finally, the bargaining power of the company or the population under study may be different than that between deCODE and Iceland. A company could face a powerful guardian of genetic information, such as the Chinese government who has power to entirely block access except on their own terms, or, alternatively, a considerably weaker body may be intervening on behalf of the population studied. Because the resources that are to be mined are inherently unique, variations in bargaining power may make analogies to deCODE less useful than they would be otherwise.

C. deCODE's Lessons

82. Keeping in mind the limitations just described, there are a few observations that can be made from examining the growth of deCODE and the effect of the company on Iceland. This subsection presents three generalized lessons that one can take away and apply in other bioprospecting contexts. The first lesson concerns the viability of bioprospecting as an industry. The relatively strong economic and scientific success of deCODE suggests that target populations should be demanding a larger piece of the bioprospecting pie; the industry is not as frail as was once hypothesized. The second lesson counsels that target

²⁸⁵ Hollon, *supra* note 273, at 1.

²⁸⁶ Taubes, *supra* note 155, at 41.

populations should consider tethering a company geographically to the place where the people under study are located. As shown in Iceland, tethering increases the economic rewards of the population under study as well as allowing for effective ethical oversight. Finally, the ethical debacle that has resulted from the Health Database Act should act as a warning to other bioprospecting companies. Bioprospecting arrangements that are offensive to ideals of confidentiality and self-autonomy invite repeated attacks that can threaten the viability of the project.

1. Bioprospecting Can Deliver Profits and Meet Scientific Goals, Suggesting that Populations Under Study Should Demand Compensation

83. When deCODE began in 1997, the viability of deCODE's business model was mostly unknown. The risk of failure appeared great enough that one could argue that the bioprospecting company should receive a majority of the upside of any arrangement as a risk premium. Had deCODE only isolated a single gene, or not found anything at all, one could argue that bioprospecting companies should continue to extract all the profits from their investments in such long-shots. Instead of failure, however, deCODE has been quite successful in its endeavors. The economic and scientific growth of deCODE suggests that the risks of bioprospecting are not as great as once imagined. Not only has deCODE found genes for at least three diseases, and narrowed down the genetic culprits of several others, but it has done so faster than studies involving heterogeneous populations.²⁸⁷ The company's numerous discoveries help to substantiate the scientific theory that mining sufficiently homogenous populations accelerates the discovery process. The DNA of the Icelanders has in some way proven its worth to deCODE. Based on deCODE's experiences, as well as that of other early genome miners,²⁸⁸ it stands to reason that other homogenous populations similarly may generate successful results.
84. From an economic perspective, deCODE has also demonstrated an ability to generate a profit and sustain investor confidence. At the time of its incorporation, deCODE's reception in the established pharmaceutical community and in the market was uncertain. The company has since forged alliances, recovered from a stock market drop, and built a company valued at hundreds of millions of dollars. A bioprospecting company that begins today can be assured that it can find investors and partners, given a valuable enough DNA resource.
85. Bioprospecting has a high degree of volatility and risk that cannot be dismissed by referencing the successes of deCODE, however. The company has failed to produce a tangible product, even after five years of research. This suggests that increased patience is needed with bioprospecting companies. Finding a gene is only a small step toward developing a diagnostic test, which in turn is a far cry from developing a treatment. Economically, deCODE also remains a higher risk stock and the company has not yet generated a profit. Investor confidence was shaken by the tech bust, and the nature of deCODE's partnership with Roche is now focused more on production than on basic

²⁸⁷ See, e.g., Matthews, *supra* note 175, at 20 (discussing the rapid find of the FET chromosome.)

²⁸⁸ Myriad Genetics is one prominent example. The company developed a diagnostics test for two breast cancer mutations after studying Mormon families, who, like Icelanders, keep accurate genealogical records. Blanton, *supra* note 278, at 10.

research. Should the company fail to make headway in developing products, its revenues from Roche will begin to dry up. Using deCODE as an example, bioprospecting companies have a great potential for short term market acceptance and success in finding faulty genes, but their long term prospects of product development and sustained growth are simply less certain.

86. Overall, the first lesson that can be learned from deCODE is that the DNA extracted by bioprospecting companies has some worth. The value of a bioprospecting company hinges on the DNA it collects; mining techniques of course play a part in discovery, but the company can only uncover what is latent in the genes. The relative success of deCODE proves that searching the genes of homogeneous populations is a worthwhile investment—it generates scientific and market success, even if more lucrative success remains elusive.
87. Recognizing that the DNA has value is one thing, but deciding the value of the information is much more difficult. Iceland receives three forms of compensation for access to its people's health records, but nothing is paid for access to the genetic information volunteered by Icelandic people. The Health Records Database Act allowed Iceland to regulate deCODE in a way that it could not otherwise do.²⁸⁹ If Icelanders wished to give away their genetic information for free to deCODE, there was no method for the Iceland government to intervene. By offering an additional service to deCODE, Iceland thus finally was able to extract some value for its people. Iceland's compensation consists of lump sum payments for the health records license with a portion of profits, free medicines should they be developed, and the indirect effects associated with having deCODE remain in Iceland to employ native Icelanders and spawn competition in the biotechnology sector. At the time that deCODE and Iceland formed their agreement, giving deCODE the benefit of the risks may have been appropriate. As things have developed, however, Iceland's direct payments are decisively paltry. The Icelandic government currently receives only \$700,000 a year from deCODE despite the company's \$600 million dollar valuation. The money received from Roche and deCODE's IPO has been funneled into research and development without increasing the payment to the people who make the database possible. Even if deCODE does make a profit, triggering the profit sharing clause of its license, Iceland will never receive more than \$1.4 million per year. Capping the profit percentage denies Icelanders most of the benefits should the company experience even greater financial success. The devaluation of the contribution made by the Icelanders may be compensated by the promise of free medicines. It should be recalled, however, that Iceland did not negotiate for free medicines. The benevolence of deCODE and Roche is responsible instead for the promise. The indirect contributions to Iceland may be the most rewarding and will be explored in the next subsection.
88. Even taking a muted view of deCODE's success, Iceland appears to have undervalued its contributions to deCODE. Future target populations may want to adopt some measures to ensure that they will adequately benefit when a private company succeeds by using their genetic resources. One such method would be to extract a true percentage of profits

²⁸⁹ *POPULATION, INC.*, *supra* note 16, at 50.

without a cap. The population would thus receive the full value of their DNA—should their DNA lead to great discoveries and wealth, they would be highly compensated, while a more modest success would garner only modest rewards. Another method of compensation would be to demand free medicine or diagnostic treatments. A small population may more easily extract such an agreement than a larger population, however. Giving medicines to 285,000 Icelanders would be reasonable given possible sales around the world, but such a promise to all billion Chinese would deny the company a large proportion of their possible sales. There is also the further problem that a treatment may only work for the target population. As discussed previously, a drug developed based on Icelandic genetic information simply may not work outside Iceland. Promises of free medicines and diagnostics thus may encounter more resistance by companies. A final method of compensation for the value of their genetic information is tethering the company's activities to the community under study. While the benefits are indirect and difficult to quantify, tethering can have significant positive effects for a population.

2. Tethering Creates Substantial Rewards to the Host Country

89. In its contract with deCODE, Iceland requires that the company keep many of its health database activities inside the country's borders. Such tethering has been shown to provide many benefits to Iceland. A second lesson to learn from deCODE's relationship with Iceland is that geographical constraints on a bioprospecting company can extract value for the people being researched.
90. Remaining in Iceland forces deCODE to interact with the population it is studying and give back to them economically and intellectually. In becoming a large employer of educated workers, deCODE has enabled Icelanders trained in the sciences and management to remain in their home country. The company gives opportunities for employment and skill enhancement that an Iceland native typically would not find. Iceland thus retains and even brings back some of its best and brightest achievers instead of losing them to countries with more established biotechnology industries. Given the dependency of Iceland on agriculture and fishing, the creation of a high technology sector also diversifies the Icelandic economy and makes the country more attractive to outside investors. Finally, employees of deCODE may use the experience to launch other biotechnology ventures and otherwise branch out and grow the biotechnology sector in the country. The presence of deCODE in Iceland has already provoked other scientists in the country to form UVS to compete with for the nation's bioprospecting riches.
91. Tethering also has helped Iceland oversee the use of the health records and genetic databases by deCODE. The country can monitor the scope of the use of the database because deCODE is within easy geographical access; officials can review its files, its laboratories, and its clients at the firm's headquarters near Reykjavik. Iceland can terminate deCODE's license for breaches of confidentiality, but that right would be worth far less if Iceland could not detect such breaches. The Icelandic government currently plays a large part in the collection and recording of data, involving itself in the day-to-day activities of the company in a way that prevents deCODE from engaging in behavior that may harm Icelanders. Government officials code patient data to protect confidentiality. They also physically control deCODE's access to the master list of the company's own

genetic database. The guardianship activities by Icelandic officials would be exceedingly costly if deCODE were in another country. The ability to keep deCODE within its borders thus helps Iceland control the company's use of its people's information and also allows the country to do the best it can to protect the privacy of donors.

92. Targets of biotechnology companies may benefit substantially by following Iceland's example and using tethering techniques. Allowing access to modern employment opportunities reverses the brain drain common in many countries and also provides a way to increase economic status and prestige. Keeping a bioprospecting company near its research subjects may even spark competition and industry growth in places that need economic recovery. Tethering also mitigates the exploitation via helicopter genomics by requiring companies to form ties to the target population and provide opportunities for employment and advancement of the people under study. The bioprospecting companies are prevented from hoarding all of the profit; from the construction of a laboratory in the host community to the hiring of native scientists, tethering disgorges money from the company in an effective and productive manner. The work gets done and both the target and the company can benefit.
93. Just as important as the economic benefits, tethering also allows for effective oversight of the use of genetic information and can help deter misuse by the company. As in Iceland, a community that has the ability to monitor a bioprospecting company has a better chance of ensuring confidentiality of that information, preventing discrimination, and otherwise protecting its citizens from the hazards associated with genetic profiling.

3. Ethical Issues May Ground Bioprospecting Projects Unless Adequately Addressed

94. While tethering may act to deter some unethical behaviors by bioprospectors, one final lesson to learn from deCODE is that unresolved ethical dilemmas can wreak havoc on both the company and the community under study. Bioprospecting often presents a choice between scientific achievement and the protection of the individual. The way that deCODE and Iceland currently handle the creation of the health database has not quieted the fears of the individual sufficiently.
95. Because of the presumed consent provisions of the Health Database Act, Icelanders suffer not only the possibility of exposure of their genetic data, but they also experience a constraint on their ability to choose their level of self awareness. In Iceland, confidentiality remains a key concern for the studies done by deCODE, even with the establishment of a host of complicated protocols described in Section II. Simply put, the homogeneity of Icelanders which makes the database valuable also makes identification of an individual donor all too possible given how few Icelanders exist. The possibility of discrimination based on genetic information creates a compelling need for ensuring anonymity. Even with the best of security features, however, Icelanders would still have cause for concern. Issues concerning self-autonomy are implemented when a technology may reveal more about a person than they want to know. Even with an opt-out provision, the government has still chosen a default method of including every Icelanders into a megadatabase that is invasive and ultimately predictive of future health.

96. The ethical problems associated with the Health Database Act have yet to be alleviated or forgotten. Three years after granting deCODE the database license, critics of the Act still continue their quest for annihilation of the legislation. The publicity associated with the ethical crisis detracts from other important assets of the company—the genetics and genealogical databases, which have been acquired through informed consent and general public knowledge. The CEO of deCODE continuously must defend the Act and his company from attack, taking time away from managing the company.²⁹⁰ The damage to deCODE is obvious. The ethical opposition has hampered the creation of the health records database in a variety of ways. Unwilling doctors and opt-out Icelanders limit the size of the database, and judicial and administrative claims add even more pressure to the project. Even though the Act was democratically approved, winning favor in public opinion polls as well as in the Alþingi, the ethical questions cannot be done away with on a majoritarian basis. Moreover, other ethical critics from around the world, especially in Europe and America, have joined the Icelandic dissenters in assailing the Act. Ethical concerns can cross geographic boundaries and arouse outsiders who lack any connection at all to the company or its research targets. The fear that the unethical behavior could spread in the future is enough to draw critics regardless of the desires of the original parties to the agreement.
97. Bioprospecting companies should consider what has happened with the Health Database Act as a warning. Ethical short-cuts can slow a project's progress and bring ire from the world. Presumed consent is only one such landmine that has been uncovered. Questions about what constitutes informed consent, as well as how to best respect privacy and confidentiality, are other issues that can create a deCODE-like backlash. Given the potential damage that may result to both the researchers and their research subjects, both parties should carefully consider how to best and most ethically pursue a bioprospecting project. Security and protection against discrimination is only one perceived harm to avoid. Individuals also must be given a free choice to participate, and perhaps must be getting enough from the deal to make the relationship appear a fair bargain. The attacks by Mannvernd do drop the word “monopoly” alongside cries of moral condemnation after all.²⁹¹ While research subjects who wish to cure deadly diseases truly may not “miss the blood drops [they] donate,”²⁹² the deCODE controversy counsels that a company should be extremely careful in examining the ethical ramifications of its agreements.

V. Conclusion

98. Iceland and deCODE illustrate a complex bioprospecting arrangement that has both advantages and disadvantages. This paper is a case study, providing a snapshot of a prominent bioprospecting firm and the people it has studied. In analyzing deCODE's business model and its current economic and scientific position, the goal has been to enable a critical evaluation of the arrangement. A similar goal of evaluating the Health

²⁹⁰ See, e.g., John Greenwood, *Decoding Iceland's Genes*, THE NATIONAL POST, Mar. 18, 2000, at D1.

²⁹¹ Berger, *supra* note 158, at 11.

²⁹² Frick, *supra* note 16. The quote comes from a woman afflicted with osteoarthritis who had just broken both her legs because of the disease. She explained that she “would be willing to go to great lengths if it would help” and hoped for a brighter future for her grandchildren who may one day also suffer from osteoarthritis.

Database Act and Iceland's benefits has also been undertaken. The 2002 snapshot of deCODE shows economic and scientific trends toward success that are encouraging for the bioprospecting industry. The success experienced by deCODE suggests that bioprospecting companies can well afford to compensate their research subjects in some manner, and that target population may wish to make increasing demands on bioprospecting companies in exchange for their valuable genetic information. The study of deCODE also reveals that the most effective compensation may be different than a straight fee arrangement. Profit sharing, free medicines, and tethering also create value. Iceland's ability to require deCODE to conduct many of its activities within the country's borders has helped the country's economic and intellectual health. Tethering a company to the community can provide jobs and build technological savvy, diversifying the economy and retaining skilled workers. Given that bioprospecting thrives in small enclaves and out-of-the-way locales, the access to technology and high-level employment opportunities may be worth much more to the target population than a set fee.

99. In evaluating deCODE and Iceland, one can also see the obvious problems that have arisen out of population genetic research. The company still faces an uphill battle to produce marketable products and can easily slide in the stock market if the pace of discovery continues to drag. The implication is that target populations may not be able to demand too much from the still risky bioprospecting industry. A more complex problem has been the ethical dilemma posed by the presumed consent provisions of the Health Database Act. The fear of confidentiality breaches, combined with a sense of usurpation of free will, drives a massive attack on deCODE and Iceland that has continued since the Act's passage. The vociferousness of the debate easily leads to a conclusion that certain ethical issues cannot be solved through democratic voting, force of will, or even the testing of time. Despite the best efforts by the Icelandic government and deCODE to explain the security and desirability of the opt-out requirements, acceptance has not yet occurred.
100. The bioprospecting industry continues to expand, seeking out populations hidden away by nature, like the Icelanders, or hidden away by choice, like the Amish. Along with the expansion comes a host of questions about exploitation, cooperation, and ethical science. In reaching the right mixture of scientific advancement and individual rights, the examination of specific bioprospecting arrangements allows the whole field to learn from mistakes and expand on innovations. The Icelandic experience with bioprospecting provides a series of lessons for the future and for others. In 1882, a traveler to Iceland remarked on the connection between Icelanders and the rest of the world:

In some sort we may look upon ourselves as [the Icelandic's] representatives in the modern world; we have inherited, with a strain of their race, their spirit of enterprise and their love of the sea. Everything relating to them has therefore a special interest for us; and when we inquire into their history we find that Iceland holds the key to the knowledge we desire to gain.²⁹³

101. Over a hundred years later, Icelanders are continuing to provide knowledge, driven by the

²⁹³ OSWALD, *supra* note 1, at 280.

same “spirit of enterprise” that has characterized the country throughout its existence.