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The case of Decode Genetics

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GENETIC TECHNOLOGY
AND THE EVOLUTION OF PROPERTY RIGHTS:
THE CASE OF DECODE GENETICS

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Abstract: Recent advances in biology and genetics have raised the value of life samples, health records and genetically modified micro-organisms, and, as Demsetz (1967) predicts, rising values increase the demand for well-defined exclusive ownership rights. But greater expected value of resources also fires up various claimants who compete in political, judicial and ideological domains to advance their interests. I illustrate the complex evolution of property rights in modern biotechnology (and in other fields) by analyzing the well-known case of Decode Genetics, a for-profit research firm that tried to collect all of Iceland's health records into a central electronic database. Decode Genetics fought two rounds with the informal owners of the health records—the country's medical establishment. The first round focused on formal institutions. In the second round, which involved informal institutions, the insiders managed to block the national databank project. Yet, the firm became renowned for its research into the genetic causes of major diseases. The paper shows that Decode Genetics was able to carry on by switching to a new game plan. Under the new strategy the firm relies on Coasean bargaining to acquire necessary genetic material and health records.

Keywords: biogenetics, property rights, technical change, Iceland, health sector database, privacy, informal institutions, Coase Theorem, Decode Genetics

JEL Classification: D23, K11, L51, O32, O38

1. Introduction

New technologies are a major force propelling the evolution of property rights. Technical change often increases expected value of assets and creates demand for redefining and strengthening exclusive ownership rights (Demsetz 1967).¹ When the cost of transacting is low, the adjustments are sometimes made through private transfer of rights or Coasean bargains—if the law permits (Coase 1960). High transaction costs, however, can block private agreements, which leaves the task of adjusting property rights entirely to regulators, courts, and legislatures. Government agents may (or may not) try to direct property rights to their most valued uses but special interests often intervene and create inefficiencies (Liebecap 1989). There are other complications. New technologies and new social institutions may clash with cultural values and set the stage for norm entrepreneurs and competition among social models (North 1990; Eggertsson 2005). The discoveries of modern medicine and the Genomics Era, for instance, have increased demand for body parts, biological samples and health records, raising ethical questions about transactions in such resources.

In this paper, I examine the impact of an invasive new technology on institutions using as a case study the attempt by Decode Genetics to build a national health sector database for Iceland. Decode Genetics (hereafter either Decode or Decode Genetics) is a private for-profit corporation established in 1996 with the goal of discovering the genetic causes of major diseases and their cures by analyzing Icelandic genetic, genealogical and health data.² The firm's decision to operate in Iceland may seem surprising but one can think of several reasons

¹ Causation also runs in the opposite direction. North (1990) emphasizes that sustained economic growth is characterized by continuous interaction between the structure of property rights and physical production technologies.

² Decode Genetics has also been involved in comparative studies that use biological and health data from various regions of the world.

why it decided to use Icelandic resources: (a) The small nation has kept comprehensive health records covering two or three generations, with some records going back to the early years of the 20th century; (b) Similarly, there are available extensive genealogical data spanning 3-400 years for virtually the whole nation, and in some instances going back to the High Middle Ages; (c) The genetic structure of the population is relatively homogeneous and the Icelanders are closely interrelated;³ These characteristics, apparently, simplify the task of identifying the genetic causes of disease.⁴ (d) Finally, Kári Stefánsson, the chief architect of the Decode project and its CEO—a former professor at Harvard University’s Medical School—was born, raised, and educated in Iceland and probably anticipated a friendly regulatory environment as well as a cooperative government and public in his native country.⁵

The organization of the paper is as follows. In *Section 2*, I introduce background material and briefly discuss the origins of Decode Genetics and the company’s initial strategy for accessing Iceland’s national health records. Decode persuaded the government to introduce a bill in Parliament, tailored to the needs of the firm, that called for an electronic health sector database (HSD) supervised by a licensee. At home and abroad, the Iceland HSD proposal set

³ The country was settled around AD 900 by Nordic and Celtic groups and there was virtually no further immigration until the 20th century. The population has a relatively homogenous gene structure and virtually all the Icelanders are closely or distantly related, if one traces the family trees back about eight generations.

⁴ It is conceivable, however, that the Icelandic genome is unique in the sense that genetic and medical results found by studying Icelandic data are not applicable to (all) other human groups. These issues are not fully understood.

⁵ Information about the firm is available on its homepage: <http://www.decode.com> For an account of the origins and early development of Decode Genetics see Nicolas Wade. *Scientist at Work/Kari Stefansson; Hunting for Disease Genes in Iceland’s Genealogies*. New York Times, 2002, June 18.

off an angry debate about medical ethics and privacy rights. *Section 3* examines the initial local opposition to Decode's entry on the Icelandic scene. The opposition was organized to a large extent by insiders or "firms" (health sector organizations) that were already in the market. The insiders sought support both at home and abroad. Several international experts on ethics in medicine answered the call and criticized the Decode project both in their scholarly papers and protest letters to the media and various scientific bodies.⁶

The first stage of the game focused on formal institutions. In the spring of 1998, when the HSD Bill was introduced in Parliament, the opponents attempted to put the Bill to sleep or radically change it. A revised and weakened version of the Bill was passed into law toward the end of 1998. *Section 4* discusses the second stage of the game, which followed the passage of the HSD Act and focuses on informal institutions. I claim that the insiders captured the public Data Protection Commission, which under the HSD law was given the role of encrypting medical records destined for the HSD. The insiders also mobilized health sector workers, who refused to transfer 'their' health records to the HSD. These strategic victories by the insiders forced Decode to abandon the HSD project.

The insiders also tried to turn public opinion against Decode, knowing that the firm had no hope of surviving if patents, their relatives and others refused to cooperate in its research projects and provide blood samples and various other information. In the public relations battle Decode was the winner; the campaign to delegitimize the firm failed and did not seriously undermine its strong public support. *Section 5* explains how Decode Genetics, without the HSD, became a world leader in its field. The Coase Theorem (Coase 1960)

⁶ See, for instance, Árnason, V. (2004) for references to this literature.

suggests the answer: Overcoming uncertain property rights and substantial transaction costs, Decode managed to access necessary inputs through Coasean bargaining.

2. Decode Genetics Moves First: A Proposal for a Health Sector Database

Decode Genetics is the creation of a former Harvard University professor of neurology, neuropathology and neuroscience, Kári Stefánsson, who was born, raised, and educated in Iceland.⁷ The corporation, which is registered in Delaware, operates primarily in Iceland and uses mostly Icelandic data to search for genetic causes of several major diseases and eventually their cures. In this paper, I am not concerned with scientific aspects of the project but with the evolution of formal and informal property rights following Decode's entry on the Icelandic scene. I interpret the battle between Decode and health sector employees, which drew world attention, as a struggle over property rights to the country's health records. Unlike many observers, I do not interpret the Decode episode as a conflict over privacy rights, commercialization of science or free access to scientific data.⁸ I begin with a brief discussion of Iceland's health records.

Since early in the 20th century, health workers in Iceland have systematically collected and stored information about their patients, using storage systems ranging from files containing handwritten notes and memos by physicians to sophisticated electronic databases.⁹ The files contain general health records, standard byproducts of healthcare activities, and also

⁷ Stefánsson received his M.D. and Dr. Med. from the University of Iceland. Prior to his time at Harvard University, he held faculty positions at the University of Chicago.

⁸ See footnote 6 for references to these other views.

⁹ The country has had a unified health system since 1915.

specialized information collected by enterprising scientists, such as medical records of patients with heart disease. Prior to the entry of Decode Genetics, the privacy of health records had low salience in Iceland. Scientists who used personal medical data in their research typically paid little attention to the privacy of their patients and neither did the patients show much interest in the matter. In the years since 1997, new legislation has clarified the privacy rights of patients and introduced or strengthened official commissions that regulate medical research, especially the Data Protection Commission and the Science Ethics Commission. These developments were in part stimulated by the Decode debate.

The authorities had also paid little attention to the definition and enforcement of ownership rights to medical records and life samples. Uncertain formal rights of ownership had given collectors of medical records and their organizations informal or *de facto* ownership rights to these resources. The entry of a very large competitor, Decode Genetics, which enjoyed government support, put these informal rights in jeopardy. The *de facto* owners, many of Iceland's leading medical doctors, biochemists and biologists, are well qualified, several of them recognized internationally for their research. It is the small size of the nation, about 300,000 inhabitants, that paradoxically contributes to Iceland's relatively large stock of high-grade human capital by compelling scholars to go abroad to major medical centers and universities for their graduate education and post-graduate research.

In 1997-98 the idea of a central database for Iceland that would cover all medical records was not new. The discussion goes back to 1975, when health administrators, physicians, and scientists had suggested that a central database would be a valuable tool for administering the

national health system, improving health care, and conducting medical research.¹⁰ At the time, the government was unwilling to bear the high cost of such a project. About twenty years later they authorities received a generous offer from Kári Stefánsson and his firm to build and operate a HSD. Decode was ready to cover startup and operating costs and also pay a substantial license fee for using the data in its research. The proposal and the government's favorable response startled many of the *de facto* owners of the records. They saw Decode's offer as an attempt by the firm to usurp their informal rights and monopolize biogenetic research in Iceland.

The Database Act of 17 December 1998 authorizes a licensee to build and operate a centralized health sector database, initially for a period of 12 years. The proposed electronic database would bring together old and new records of the country's national health system. In the law, the main rights and duties of the prospective licensee are the following:¹¹ The licensee is authorized to transfer health records into the HSD upon receiving the consent of health workers and their organizations. The law is vague about the negotiations and silent about procedures and remedies in cases where the licensee and the *de facto* owners fail to agree. Although the Act does not explicitly define a role for the Ministry of Health and Social Security if negotiations break down, the Ministry has formal legal authority over the employees of the national health system.¹²

¹⁰ See notes to the Bill on Health Sector Database of 1998. Available on the *Mannvernd* website. See footnote 11.

¹¹ An unofficial English translation of the 1998 Databank Act is available on the website of *Mannvernd*, the association established by Decode's opponents:
<http://www.mannvernd.is/english/laws/law.HSD.html>

¹² Notes with the *Bill on Health Sector Database* contain the following observations: "Art. 7 states that the licensee may, with the consent of health institutions or self-employed health workers, receive information from health records for entry onto a database. In the case of a self-employed physician,

The licensee has the right to use information from the database for research but all personal data must be encrypted to prevent the licensee's researchers, and other users of the data from relating personal information to the persons in question. If the licensee violates its agreement with the Ministry, the law allows for severe punishment, including fines, loss of license and imprisonment, depending on the nature of the transgression.

Every person has the right to withdraw parts or all of his or her personal data from the HSD.¹³

As stated, the law protects the privacy of personal data transferred into the HSD by requiring encryption of the data by workers in healthcare organizations where the records originate.

The privacy principle governing the HSD project is *assumed consent*—consent is assumed until people request that some or all of their personal information be withdrawn from the database. When assumed consent is combined with encryption, the authorities maintain that

his/her consent is required. In the case of a health institution, the consent is required of those who are competent to make decisions on behalf of the institution. Consultation shall take place with the medical board and professional managers before a contract with the licensee is concluded." For source, see footnote 10.

¹³ The law does not consider explicitly whether people have the right to withdraw information about their deceased relatives from the HSD. Yet, officials concluded that the law did not grant such rights, referring to notes accompanying Article 8 of the HSD Bill that state: "The Bill does not allow for individuals being able to refuse to allow data on their deceased parents to be entered on the database." In 2003, the Supreme Court of Iceland ruled that a young girl had the right remove her father's records from the HSD. The Court argued that the girl was not empowered to act as a custodian of her father's right, but she had the right to protect herself against undesirable information about herself derived from her father's genetic data. Supreme Court of Iceland, No. 151/2003. Available in Icelandic on <http://www.haestirettur.is/domar?nr=2566>

the arrangement is equivalent to *informed consent* (informed *ex ante* consent) and consistent with international standards.¹⁴

In the law, government administrators of the national health system have unrestricted access to the HSD. Scientists who do not work for the licensee can gain access by applying to a special committee of three members, one of whom is appointed by the licensee. The admissions committee must in all cases permit access to the HSD, except when the applicants' research projects directly conflict with the commercial interests of the licensee. Users of the HSD other than the licensee pay a fee, but only a small charge to cover the variable cost of extracting data from the electronic database.

The licensee bears the full cost of building and operating the HSD. The licensee, moreover, covers the government's negotiation and monitoring costs of the project; pays an annual license fee of about one million dollars; and (in addition to regular taxes) contributes six percent of its commercial profits to the government.¹⁵

3. Round I: Competing to Influence Formal Institutions

The entry of Decode Genetics on the Icelandic scene set off a fierce struggle between the new entrant and established insiders. Initially, the struggle focused mostly on formal institutions,

¹⁴ At the time of the HSD debate, Decode's supporters and opponents argued at length and in detail about the techniques of encryption, debating whether it is theoretical possible to create an inviolable method of encryption. Árnason (2002) provides his viewpoint as well as references.

¹⁵ Although not part of the 1989 HSD Act, Decode and its collaborator Hoffman-La Roche volunteered to make all drugs discovered by using the Icelandic resource available free of charge to the nation.

and both sides tried to make their case with legislators, bureaucrats, and judges. The critics of the HSD project made two key claims: (a) through its control of access to the HSD, the licensee obtains a near monopoly of medical and biological research in Iceland; and (b) the HSD project violates basic privacy rights of patients. An opportunistic licensee is able to misuse personal information and impose serious damage on members of the public.

First, consider the privacy issue, which I interpret as a strategic response to Decode's entry by the informal owners of the medical records. The critics claimed that the *assumed consent* premise of the HSD law gave patients insufficient protection and insisted that the rule of *informed consent* should regulate the use of personal data. The method of informed consent, which requires providing each individual with explicit knowledge of all future uses of his or her personal data, is oriented toward individual research projects. Informed consent would involve high transaction costs, if used to regulate a multi-purpose HSD.¹⁶ The assumed consent approach of the HSD legislation was a compromise: an attempt to protect personal data without incurring excessive transactions costs for either patient or scientist. The approach has three safeguards: each individual has the right to withdraw his or her personal information; all personal information is encrypted; serious punishments are invoked if the

¹⁶ The word 'informed' in *informed consent* refers to a person who is informed about each particular research project for which his or her data will be used. Arnason (2004) elaborates why informed consent is logically inappropriate for the HSD. Instead, he proposes "explicit written *authorization* for participation in database research based on general knowledge about the database and the research purposes and practices." P. 44.

licensee attempts to reconvert the coding.¹⁷ When the HSD Bill had become law, the insiders contemplated testing in domestic and international courts the constitutionality of its privacy arrangements. These plans brought no significant results.¹⁸

In the privacy debate virtually the sole focus of the critics was on the HSD. For the most part, the critics ignored the security of existing data systems that were scheduled to enter into the HSD. *Mannvernd*, the insiders protest association (see later), organized a campaign urging people to sign an official form enabling them to withdraw their personal records from the proposed HSD. The association, however, raised no alarm over patient privacy in the country's other, sometimes non-encrypted, health databanks, which is consistent with the hypothesis that the dispute involved essentially ownership rights rather than privacy rights.¹⁹

Another major issue in the HSD debate concerns the possibility that the licensee would monopolize biogenetic and medical research in Iceland or at least severely limit the opportunities of scientists who were not employed by Decode. For the insiders, the challenge by the entrant has three major dimensions: Changes in the relative status of local researchers; effects on current research programs and research environments; and impact on long-term

¹⁷ Foreign scholars, often professors of ethics in medicine, who were drawn into battle over the proposed HSD sometimes lacked knowledge of the local context. Some expressed fears that private health insurance providers might refuse to insure high-risk individuals on the basis of data obtained (illegally) from the HSD. This viewpoint does not recognize that Iceland has a public national health system.

¹⁸ See footnote 13 for the single example of an unfavorable court ruling.

¹⁹ Various critics, for instance domestic and foreign intellectuals, had no economic stakes in the HSD. Their opposition, in many cases, was based on a perceived need to protect the privacy of patients or the traditional (non-commercial) norms of science. I claim that these actors played a secondary role in the game.

research opportunities in Iceland. In terms of likely changes in the relative status of the insiders, concerns about negative effect are realistic.

The sheer size of the entrant's operations and its extensive international publicity dwarfed other local research in biology and genetics. The Decode project certainly stole the limelight, at least temporarily, from leading insiders. As for the insiders' current research programs and research environments, the expected effects seem to be either positive or neutral. The enormous size of the entrant relative to the local science community could be expected to bring positive synergies and critical mass effects.²⁰ The insiders, moreover, were not about to lose control of their data. They could (a) continue to use their own (decentralized) data sources or (b) use the new HSD. There are two caveats here. With the HSD in operation, health sector workers would be under pressure to economize and discontinue costly maintenance of databases that contain material destined for the HSD. The incentive to neglect the various databases depends directly on the ease of access to the HSD. The other qualification is that the HSD Act gave Decode certain rights to exclude direct competitors from the central database. The insiders were particularly troubled by Decode's right to appoint one of the three members of the access committee, a right that the firm might abuse.

²⁰ "As of December 31, 2003, when the HSD struggle was over, Decode Genetics and all of its subsidiaries employed 414 full-time staff. Of the total number of Decode employees at the end of 2003, approximately 109 were located in the USA, and 305 in Iceland. More than 90 held Ph.D. or M.D. degrees and approximately 250 held college degrees." Decode Genetics, Annual Report, Part 2, p.25. (Available on the Decode Website.) Iceland has several small colleges but only the University of Iceland has full-scale engineering and natural science faculties. In 2003, total faculty *in all fields* at the University of Iceland numbered 420. Decode employs non-Icelandic scientists; Icelandic scientists formerly employed abroad; and researchers who were available in the local labor market. In the credit market crunch of 2008, the story has change. Decode Genetics has cut back its operations and struggles to avoid bankruptcy.

The third dimension, long-term opportunities for biogenetics research in Iceland, is in my view the most challenging aspect of Decode's entry for the insiders. When Decode entered toward the end of the last century, it was widely believed that the entrant's concept of using a sophisticated HSD for Iceland to find genetic sources of major diseases would bring scientific fame (which it did) and worldly fortunes for the investors (which, so far, it has not done). Local researchers felt that the HSD legislation potentially excluded them from this golden opportunity—excluded them, acting alone or with foreign partners, from competing directly with Decode's projects and sharing the treasures.²¹ The basic health data were already in the hands of the insiders but decentralized databanks seemed to be a poor substitute for an access to a national databank.

4. Round II: Competing to Influence Informal Institutions

The insiders lost the battle over formal institutions, although they were able to modify the terms of the HSD Bill, especially its privacy requirements, before the Bill became law at the end of 1998. About a year later, in 1999, the government signed a contract with Decode, which established the firm as the licensee authorized to build and operate a central electronic health sector database in Iceland. The passage of the law moved the game into its second phase in which the insiders relied on three complementary strategies: to (a) organize collective opposition among health workers and unite them in a refusal to transfer the health records of their organizations to the HSD; (b) capture the government's Data Privacy

²¹ When Decode sought to limit access by direct competitors to the HSD, the firm was probably concerned that large foreign competitors might try to access Iceland's valuable data, either alone or in cooperation with the relatively small local research community.

Commission and spur the Commission to reject on technical grounds Decode's complex and costly proposals for encrypting personal data destined for the databank; (c) turn the public against Decode and its projects, in particular by asking people to withdraw their personal information from the HSD by signing a special form; a device that the insiders had managed to have included in a revised version of the HSD bill.

All three strategies involve influencing social norms or informal institutions and Decode's defense was of the same nature. The antagonists assumed the role of norm entrepreneurs, each side trying to influence behavior by appealing to basic values. Árnason and Simpson (2003) provide an insightful anthropological account of the models and metaphors that the players used. The insiders, led by distinguished scientists, coordinated their strategies by establishing in October 1998 a lobby group or association, which they called *Mannvernd*, literally translated as 'Human Protection'. In the English language website of *Mannvernd* the sponsors state that the association is "a grassroots organization founded by scientists, doctors and other concerned citizens with the aim of standing guard for the rights of the citizenry."²² *Mannvernd's* website, both the English and Icelandic versions, provides comprehensive links to public documents and essays about the HSD-Decode case.

The critics relied on the argument, which is often used against for-profit biotech firms, that Decode's scientists and their American corporation undermine the culture of modern science by replacing the goal of selfless pursuit of knowledge with the goal of profit making. In fact, Decode was accused of commercializing both science and the human body. The slogan "We

²² The link to the English language homepage of *Mannvernd* is: <http://www.mannvernd.is/english/index.html>. In English the organization is known as the *Association of Icelanders for Ethics in Science and Medicine*, which is not a literal translation.

are our genes” circulated and claims were made to the effect that the Icelandic Government, in cooperation with bio-pirates, had sold our ancestors, our children and us to an American corporation.²³ The critics also expressed fears that Decode would use the health records for dubious commercial purposes other than biogenetics research. Some commentators worried that leaked data would allow employers and private insurers to discriminate against people with unfavorable genetic traits.²⁴ They also claimed that the HSD might compromise the confidential relationship between patients and their doctors, for instance in psychiatry. The worries about leaks were often linked to claims that encryption could never be fail-safe or that those involved in encrypting might be tempted to retain and disseminate sensitive personal information.²⁵

Decode fought back on many fronts. First, the firm de-emphasized the profit motive and denied that it was driven by lust for money. According to Kári Stefánsson: “What we are really doing here is setting up a big research laboratory disguised as a company. The work [done in the company] is not driven by anything else than a desire to create new knowledge

²³ For example, one scholarly essay carries the lengthy title “At Least Give the Natives Glass Beads: An Examination of the Bargaining Made Between Iceland and deCODE genetics with Implications for Global Bioprospecting” Potts (2002). The idea that the HSD was a potential gold mine was popular both with critics and supporters of Decode. At one point, a law office in Reykjavik offered to help people withdraw their information from the HSD and then sell it back to Decode. The Ministry of Health and Social Security declared that such transactions in ‘communal property’ were outside the law. Nothing came of the attempt.

²⁴ See footnote 17.

²⁵ As already mentioned, the law assigned the initial task of encrypting health information to workers in the organizations that originally collected the data. These workers already have access to the health information in their storage systems, and encrypting the data for the HSD would not add substantial new privacy risks.

which then can be used to improve people's lives, ease their pain and prevent illnesses."²⁶ In its public relations campaigns, Decode emphasized that its activities benefitted all humanity. The firm also appealed to economic self-interest. In 1998, when the HSD Bill was hotly debated in Parliament, Decode put stocks in the company on the market in Iceland. The stocks sold at an inflated price, reaching US\$ 65 per share. The share price fell sharply in the months following July 18, 2000 when Decode was registered on New York's Nasdaq Market. In 2001, the stock price fluctuated in the \$5.63 to \$12.31 range. Toward the end of 2008, the company was struggling to stay in business with the stock price well below \$1.

On yet another front, the company appealed to national pride, claiming that fate had given the Icelandic nation a unique historical opportunity. The constellation of a homogenous national genome, excellent medical and genealogical records, and a small population (which can make sampling unnecessary) had created unique opportunities for biogenetics.²⁷ Moreover, Decode took advantage of the Icelanders' preoccupation with family history. To meet its own research needs, Decode set up a separate electronic database that contains all known Icelandic genealogical records and made the information also available to the nation on the Internet.²⁸ For no charge, the Icelanders can use personal computers to trace their family trees and discover how they are related to each other. Decode named its genealogical database *The*

²⁶ From an interview in Iceland's leading newspaper, *Morgunbladid*, on 24th November 1996. Cited in Árnason and Simpson, 2003, p. 538.

²⁷ Homogeneity of human genes in Iceland is apparently associated with the country's centuries of isolation and periods of extremely high mortality rates, especially in the 18th century.

²⁸ The website of the genealogical database, www.islendingabok.is, is available only in Icelandic. It is estimated that 1.5 million people have lived in Iceland since the country was settled around 900 AD. The genealogical database includes 740,000 individuals or about 50% of the current and historical population of the country. The first population census was taken in 1703 and the database includes 95% of individuals living in the country since 1703. Source: www.islendingabok.is.

Book of Icelanders, which is also the name of a medieval manuscript that lists names of those who originally settled Iceland (around AD 900). The project thus links the country's history to the miracles of the biotechnical revolution.

Pálsson and Hardardóttir (2002) examine the debate in the Icelandic media about the HSD-Decode case. They cover 28 months, beginning in April 1998 when the HSD Bill was first introduced in Parliament. During this period several hundred articles appeared in the press and numerous television programs were aired. The authors analyze in detail 569 articles (news reports and op-ed pieces) that appeared in the country's leading newspaper, *Morgunbladid*. The statistics for op-ed essays show that for most months a majority of the writers had a negative view of HSD-Decode project. They also show that physicians wrote more op-ed pieces about the case than any other occupational group, and they overwhelmingly opposed the project. "Only in the ... category representing the general public did positive items outnumber negative ones" (Pálsson and Hardardóttir, 2002, 278).

In the second round of the game, the insiders won two of the three battles: The country's health workers refused to transfer health records of their organizations into the HSD, and the Data Privacy Commission found unacceptable flaws in all of Decode's plans for encrypting the health records and refused to cooperate in setting up satisfactory coding techniques. The insiders failed, however, in their efforts to turn the public against Decode. While the struggle lasted, *Mannvernd* reported regularly on its website how many individuals had already signed statements for opting out of the HSD. By the end of June 2003 some 20,426 individuals had opted out but almost all this activity occurred in the years 1999-2001. Decode, for its part, reports a very high success rate when recruiting people to participate in its projects. In 2002

about 100,000 volunteers (in a nation of about 300,000 individuals) had participated in more than 50 disease programs, and some 95 percent of those who were asked to participate in the projects had agree to cooperate.²⁹ A Gallup poll, paid for by Decode, found in April 2000 that 81 percent of the Icelanders supported the firm, while 9 percent opposed it, and 10 percent were undecided.³⁰

By winning the two of the three battles, the insiders succeeded in destroying the HSD project, yet Decode Genetics went on to become a world leader in its field.³¹ The paper's final section examines the destruction of the HSD and explains how Decode survived.

Section 5: A Coasean Solution

The collapse of the HSD project, as we have seen, was due to non-cooperation by two key players, the country's health organizations and the official Commission on Data Protection. Although the insiders failed to mobilize public opinion against Decode, they had a firm grip on health workers in hospitals and clinics. Virtually all health organizations refused to transfer their records to the proposed HSD. The refusals were often indirect, taking the form of disagreeing on procedures for the transfer. The HSD legislation had not provided any mechanism for solving disputes between health organizations and the licensee but the Ministry of Health has formal authority over the employees of the national health system. The Minister did not join the fray and confront the employees of the health system,

²⁹ Decode Genetics Annual Report, 2003, Part 2, page 15. Available on the firm's home page.

³⁰ Cited in Pálsson and Hardardóttir 2002, p. 278.

³¹ A check of the New York Times' electronic archives, for instance, shows that the paper reports regularly, sometimes extensively, on various discoveries at Decode Genetics.

presumably fearing the consequences. Moreover, forcing health workers to select, encrypt and transfer information from health records into a central database gives innumerable opportunities for sabotage and is not a practical solution.

The official Commission for Data Protection was the other major stumbling block. The Commission rejected all of Decode's technical plans for encrypting the health data, claiming that the methods were insecure. The Commission also refused to specify what systems of encryption would provide satisfactory protection of personal information. The behavior of the Commission and subsequent developments (see below) are consistent with the hypothesis that the insiders had captured the regulatory agency.

To understand how Decode survived without the HSD, it is important to know that the firm needed massive public support to carry on. Accounts of the Decode-HSD story often miss the point that originally the firm had planned to build three interlinked databases: the HSD; the genealogical database (which I have already mentioned); and a genetics or DNA database (mostly based on blood samples). A DNA database plays a central role Decode's research program but according to Icelandic law, the Act on Biobanks from May 2000, the use of a DNA database requires 'informed consent'—whereas the HSD law only requires the weaker 'assumed consent'.³² To obtain blood samples, Decode, required outright cooperation from

³² In 1996-97 a committee on medical ethics, appointed by the Surgeon General, drafted a law recommending that scientists who collect human life samples, such as blood samples, obtain written informed consent from the donors. At the time, Iceland had no legislation governing the use of biological samples for scientific purposes. In 1998, the Ministry of Health and Social Security, drawing on proposals made by its own working group, submitted a bill concerning the use of human biological samples in research, which was enacted into law in May 2000 (*Act on Biobanks, No.110/2000*).

the public. Even if Decode had built the central health sector database, the firm was required to obtain written informed consent from each participant in all its genetics projects.

Mannvernd, the insiders' lobbying association, therefore, posed an enormous threat to Decode. In its appeals, the association painted the firm as an illegitimate organization and implored the public to withdraw their health records from the proposed HSD and in no way cooperate with the intruder. On its website *Mannvernd* defines its goals in the following terms:³³

MANNVERND is the Association of Icelanders for Ethics in Science and Medicine.

MANNVERND is the organized opposition to the Icelandic government's Act on a Health Sector Database (HSD). The HSD is slated to contain all medical records for the entire population of Iceland. Included will be the present records, all future records and records ranging back at least 30 years. The Act permits the interconnecting of the medical records to the extensive Icelandic genealogical database as well as to a database of individual DNA genotypes. The HSD will be privately established and operated under a monopoly presumably by the American genomics company Decode Genetics of Delaware, USA, or its subsidiary, and would facilitate the company's business plan.

MANNVERND believes that this Act infringes on human rights, personal privacy, and on accepted medical, scientific and commercial standards. We believe that the Act has worldwide implications and that stopping the law should be given a high priority by the world human-rights community. The government of Iceland should be encouraged in the strongest possible terms to reconsider this legislation, and suspend its enactment immediately.

³³ <http://www.mannvernd.is/english>

When the HSD plan failed, Decode was ready with an alternative research strategy (which I discuss below) but let us pause to examine why Decode initially tried so hard to obtain the right to build a very costly national database. The first explanation that comes to mind are economies of scale. I do not believe, however, that there are important scale economies in collecting, standardizing, and storing diverse health records from disparate source for use in diverse projects. The HSD was to serve a broad range of users, including government administrators, Decode scientists, as well as other scientists in a number of fields. Without clearly defined goals, it would have been difficult to select and structure the data so as to meet the needs of Decode and these other users.

If we disregard the scale argument, I can think of two possible reasons why Decode initially pursued a national databank strategy. First, the HSD concept was an effective marketing tool. The idea of a database containing the health records of the entire population of a small exotic nation captured the imagination of the world, helped Decode market itself, find collaborators, and finance its operations. Although the HSD idea never materialized, and by 2003 it was no longer seriously considered, many scholars and reporters still firmly associate Decode and its scientific success with access to a national database.

My second (and complementary) hypothesis is that Decode saw the HSD strategy as the least-cost method for accessing the Icelandic health data. In an environment of uncertain property rights in medical records, the firm expected that the strategy of contracting with the government to build a national database was an efficient way to avoid hold-up problems and bypass difficult negotiations with the multiple *de facto* owners of the records. Operating in an

uncertain world, the firm did not foresee that the insiders would exercise their informal power; the Ministry would fail to punish the insiders for noncompliance; and the Commission on Data Protection would hold up the data transfers.

When insurmountable obstacles to the HSD strategy became obvious, Decode switched to a decentralized strategy. The main elements of the new game plan are as follows. The firm defines individual projects and their data requirements, with each project involving attempts to find the genetic base of a particular disease. The next step is to identify the informal owners of the relevant health records, the insiders, and strike a Coasean bargain with them. Decode acquires the right to use the medical records in return for cash or payments in kind and sometimes involves qualified informal owners directly in the projects. Contracts are made, for instance, with physicians who obtain informed consent from their patients, collect individual biological samples (usually blood samples), make health records available and interview patients. With these data in hand, Decode uses its genealogical database to identify relatives of the patients for inclusion in the project. The relatives (and control groups) also provide DNA data and health information.

At various stages in this process, Decode resorts to the Commission on Data Protection for encrypting the data. Neither health sector workers (as the HSD law had envisioned) nor Decode are involved in the encryption process; encryption is provided directly by the Commission. The Decode project has been rewarding for the Commission on Data Protection. Initially, the Commission was paid for examining various privacy aspects of the proposed HSD project, and in recent years a substantial share of the Commission's budget comes from its work on encrypting data for Decode's disease studies.

6. Conclusion: Happy End

We conclude on a happy note. The Commission on Data Protection has managed to solve the previously insolvable problem of encrypting health records and receives payments for coding the data.³⁴ The insiders or *de facto* owners of the health records get a share of the pie. And Decode successfully carries out its scientific projects. All three parties are enjoying a win-win-win situation. The decentralized strategy worked. Decode Genetics became a world leader in identifying the genetic causes of various common diseases. In the small and closely knit small Icelandic population, the extraordinary ease of identifying each patient group along with their relatives has favored the Decode operation. The firm has also relied on, and developed, cutting-edge technologies, including statistical software.

Decode Genetics is a for-profit research-and-development firm, a new business form that the biotech era has generated. Until recently, R&D activities typically took place in divisions within large enterprises—or were carried out in university laboratories. Many economists question the viability of the new business model (Nelson, 2008). Identifying the genetic sources of diseases is for Decode only the first step toward a profitable operation. The second step requires the firm either to license the invention or develop and manufacture drugs that cure the diseases. Drug production, however, is a long and uncertain process that usually involves a series of setbacks before a successful product emerges. Decode has had excellent

³⁴ Source: website of the commission: <http://www.personuvernd.is>

success with the first task but so far has failed to complete the second step, which is a common fate for many comparable firms.³⁵

³⁵ See Decode's home page, <http://www.decode.com> for the current status of the firm's disease-gene research. In 2008 financial difficulties had slowed down Decode's drug development program and the firm has increasingly emphasized marketing DNA-based tests for estimating individual risks of developing common diseases.

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