The Public Domain in Genomics[1]

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The public domain has played a conspicuous role in the race between public and private sector initiatives to complete the sequence of the human genome. The issue of whether the human genome will be freely available or controlled by private firms as a proprietary resource has captured the attention of the public, or at least the media. Three recent stories in the press suggest that there is much at stake in policy debates over the relative merits of free access to genomic information in the public domain versus licensed access under proprietary contraints. First are the leaks and revelations concerning the unsuccessful (or at least not yet successful) efforts of the public and private sectors to join forces to complete this monumental scientific achievement together.[3] Second is the joint statement of U.S. President Bill Clinton and British Prime Minister Tony Blair that "[r]aw fundamental data on the human genome, including the human DNA sequence and its variations, should be made freely available to scientists everywhere,"[4] and the sharp reaction to this announcement in the financial markets.[5] Third, and less remarked, is the announcement by a consortium of private pharmaceutical firms that they are willing to provide funding to assemble the deluge of human DNA sequence information from the publicly-funded human genome project, evidently at the behest of the public sponsors, in order to accelerate the completion of the Human Genome Project in the public domain.[6]

The first and second stories, although extraordinary for both the high-level of attention to a seemingly arcane issue and the frantic reaction in the capital markets, are relatively easy to cast in familiar terms. Governments that sponsor scientific research might plausibly choose to put research results in the public domain in order to promote widespread access and use. At the same time, private firms investing in similar research stand to benefit more from private appropriation of information as intellectual property than from its free availability. Consequently, unrestricted access to free information in the public domain threatens the profit potential of private firms that are involved in generating and providing similar information,[7] while the private appropriation of information as intellectual property undermines the government's goal of ensuring widespread access. From this perspective, it is unsurprising that the public and private sector genome efforts would have difficulty working out their differences. The reaction of the capital markets to the Clinton-Blair exhortation to make sequence information freely available, although perhaps excessive in its magnitude and breadth,[8] is generally consistent with this story of a divergence between the competing interests of the public sector in free access and the private sector in restricted access.

The third story, involving private sector efforts to accelerate the release of genomic information in the public domain, is somewhat more unusual, suggesting a more complex relationship between private research funding and the public domain. Private benefactors of the public domain are hardly unprecedented, even in the field of human genomics.

Two notable examples are the Merck Gene Index, a privately-funded initiative to create a public domain database of partial sequences for genes expressed in human tissue,[(9)] and the SNPs consortium, a joint funding initiative of major pharmaceutical firms and a private foundation to provide a public domain collection of single nucleotide polymorphisms, or points of variance in the human genome.[(10)] The latest episode, the details of which remain uncertain at this writing, evidently involved a plan for the SNPs consortium to provide additional funding to a private firm, Incyte Pharmaceuticals, to accelerate assembly of the human genome sequence for the publicly-sponsored Human Genome Project. According to an account in USA Today, Incyte claims to have submitted a bid to do the job at less than cost,[(11)] raising the question of what both Incyte and the SNPs consortium have to gain by lending this sort of subsidy to the task of completing a public domain version of the human genome sequence. This plan, like other private sector efforts to enhance the public domain in genomics,[(12)] has been characterized as a "spoiler" strategy aimed at undermining the investments of commercial rivals[(13)] rather than a public-spirited effort to promote scientific progress by enriching the public domain.

The juxtaposition of these and related stories reveals complex and interrelated reasons for putting genomic information in the public domain-and for filing patent applications-in the public and private sectors. Although some media accounts of the race between Celera and the Human Genome Project paint a black-and-white picture of a private firm racing to profit from the genome through patents while the publicly-funded research project struggles to forestall those private claims by putting information in the public domain, in fact the picture is more variegated on both sides of the public-private divide. Celera has repeatedly promised that it will eventually make the raw sequence of the human genome available to scientists free of charge,[(14)] although the timing and details of this commitment are unclear and seem to be shifting.[(15)] At the same time, although the public sponsors of the Human Genome Project have repeatedly affirmed the importance of prompt and free public access to raw genomic sequence information,[(16)] a recent article in the Wall Street Journal reports that the U.S. government holds more patents on DNA sequences than any private firm.[(17)] That the strategies of these two initiatives for dissemination and appropriation of DNA sequence information should overlap is unsurprising given the increasingly blurry boundaries between academic and commercial research in genomics. Yet there remain important differences in the missions and priorities of different institutions in the public and private sectors with an interest in DNA sequences that have important strategic consequences.

What motivates these different players to put information into the public domain? What are they trying to accomplish? How do their motivations affect the timing and quality of their information disclosures? It is somewhat artificial, but nonetheless useful, to distinguish between the public and private sectors in attempting to analyze the multiple reasons for placing genomic information in the public domain.

From the perspective of the traditional research science community, it is hardly surprising that the government, academic, and nonprofit institutions associated with the publicly-funded Human Genome Project would make the DNA sequence information that they

generate publicly available. Indeed, prior to passage of the Bayh-Dole Act in 1980 and subsequent related statutes promoting the patenting of government-sponsored research results,[(18)] the reasons for public disclosure of scientific research results by these institutions would have seemed trivial. These traditional arguments for placing research results retain considerable normative force in the scientific community today, and the private firms involved in DNA sequencing-relying on collaborations with leading scientists-are also sensitive to the norms and incentives of research science. But in the post-Bayh-Dole world, the arguments for and against public disclosure research results have become considerably more complex, as academic and private institutions pursue overlapping research goals, mindful of the interaction between the public domain and the patent system.

Reasons for making public disclosure of research results

Scientific recognition and credibility. Publication of new research results to the scientific community confirms that researchers have achieved what they claim, triggering scientific recognition. At the same time, public disclosure subjects research results to scrutiny by the larger community, exposing errors and promoting confidence in the validity of the results. These considerations are particularly important for controversial research claims and for research under conditions of rivalry, when skeptics or rivals are likely to contest what was accomplished and when it was done.

The prospect of scientific recognition is undoubtedly motivating both academic researchers and private sector researchers involved in the race to complete the sequence of the human genome. The perennial rivalry to establish priority of scientific discovery is aggravated in this particular context by public statements from each side that the other side is pursuing a scientific strategy that will not allow them to complete the job.[(19)] To the extent that these rivalrous research efforts depend on access to top scientific talent to achieve their goals, their sponsors cannot ignore the motivations of the scientists. The price of recognition in the scientific community is public disclosure of research results. This may explain why Celera, a firm that hopes to profit from selling access to proprietary databases of DNA sequence information, has consistently promised to make the raw DNA sequence of the human genome freely available. Absent such public disclosure, their claims to priority in completing this monumental scientific achievement will be impossible for the scientific community to assess.

Researchers have expressed skepticism about the claimed accomplishments of private DNA sequencing efforts that do not make their data publicly available. Proprietary databases of sequence information are only available to private subscribers who pay for licensed access to the data; these researchers may not be the most credible scrutinizers of claims about the completeness or accuracy of the information in these databases. When researchers make their results freely available in the public domain, the results become available to hostile rivals as well as to sympathetic clients and collaborators, fortifying

the credibility of claimed accomplishments. Because of public disclosure, the scientific community is more willing to give credence to the claimed accomplishments of the public sector DNA sequencing efforts than to the claimed accomplishments of their counterparts in the private sector. Scientists often must rely on press releases and rumors for information on the contents of the proprietary databases, and those sources have limited credibility in the scientific community.

Scientific credibility was also cited by members of the SNPs Consortium as a reason for making information about single nucleotide polymorphisms in the human genome freely available in the public domain. The pharmaceutical firms in the SNPs Consortium hope to use these polymorphisms as pharmacogenomic markers that will help them gain regulatory approval to sell drugs that are safe and effective in some patients but dangerous or ineffective in others. If the patients who stand to benefit from a drug may be distinguished from those who stand to be injured by it through the use of diagnostic markers that predict drug response, the firms hope that the FDA might be persuaded to approve the drug for sale to genetically screened patients. They expect that regulatory approval for such products will turn on the scientific credibility of the test, which they hope will be easier to establish if the test uses markers that are subject to challenge and validation in the public domain.[(20)]

Widespread dissemination and use. Apart from concerns about recognition and credibility of research claims, some research sponsors can plausibly claim to favor free disclosure of DNA sequence information in publicly available databases as a means of promoting dissemination and utilization of research results. Widespread access to DNA sequence information might make sense as a way of advancing private interests as well as the public interest. There is much to say for the public domain as a way of promoting dissemination and utilization of information. The public domain is accessible to everyone without the need to get and pay for a license, making access cheap and easy. Cheapness is particularly important for promoting access by impecunious users, like academic researchers. In addition to eliminating access fees, placing information in the public domain minimizes transaction costs. It is not necessary to keep track of who owns what and who has used what-whoever finds the information valuable is free to use it without having to identify an owner and seek permission. Presumably, ease of access and cheapness will make use more attractive and more widespread. More people will get discoveries that are made freely available in research, and more people will have an opportunity to use them and build upon them in future research.

A slightly more venal variation on this argument makes sense from the perspective of public research sponsors that invest in the creation of resources such as genomic information that are likely to be widely used in subsequent government-sponsored academic research: the government is going to pick up the tab for future activities making use of this information, and it doesn't want the tab to run too high. If genomic information is held in proprietary databases or can only be used under the terms of patent license agreements, government research sponsors are going to have to pay more in the future for further research that makes use of that information than it would if the information were freely available in the public domain.

Some private research sponsors might also find it in their best financial interests to invest in generating DNA sequence information for the public domain as a means of promoting widespread access to that information. Pharmaceutical firms that profit from developing and selling drugs might believe that they will earn greater profits at an earlier date by accelerating progress in fundamental biological research, thereby bringing new drug targets into view. Rather than trying to do this fundamental research themselves (an expensive job at which they have no comparative advantage), they might be happy to have it done by universities working with public funds. To the extent that free access throughout the scientific community facilitates this sort of pre-market research in universities, pharmaceutical firms may find their interests aligned with the interests of public research sponsors in promoting free disclosure of DNA sequence information in the public domain.[(21)]

Defeating potential patent claims. There is yet another consideration that seems to be motivating public disclosures of genomic information in both the public and private sectors, and that is a wish to prevent patenting of DNA sequences. This seems to be driving the accelerated timetable for disclosure of new DNA sequencing results in a publicly accessible database within 24 hours under the so-called "Bermuda rules."[(22)] This accelerated timetable makes it difficult for grantees to get patent applications on file prior to public disclosure, much less to sort through newly identified sequence information to figure out if it includes any sequences that are worth patenting.[(23)]

In addition to making it difficult for publicly-funded investigators and their institutions to file timely applications for patents, the Bermuda rules also lead to the prompt creation of "prior art" that could potentially defeat patent claims based on similar DNA-sequencing efforts in the private sector. Noone can get a patent on something that was already publicly disclosed before the patent claimant discovered it.[(24)] A research sponsor might want to create patent-defeating prior art for all the reasons that it wants to put information in the public domain in the first place. The creation of patent-defeating prior art is a more durable way of accomplishing the same thing. If the goal is to put information in the public domain and have it stay there, that goal would be defeated if other institutions were able to get patents that remove that information from the public domain. But the patent-defeating goal does not overlap perfectly with the public-access goal, and if one of those goals dominates the other it may have strategic implications.

The creation of prior art may prevent the issuance of patents not only on the completed discoveries that are made freely available in the public domain, but also on future discoveries that become obvious in light of what has been publicly disclosed.[(25)] In a forthcoming article in the Michigan Law Review, Professor Gideon Parchomovsky argues that the prospect of preempting the patent rights of a commercial rival may motivate firms that are losing an ongoing patent race to publish their research results.[(26)] The theory is that a firm that is about to lose a patent race would be better off publishing research results that are not yet complete enough to allow the firm to obtain its own patent, but that might nonetheless be sufficient to make the rival's more complete research results obvious and therefore unpatentable. Preemptive publication permits both

firms to compete in the market for the unpatented product; otherwise, the rival will win the patent and the losing firm will be excluded from the market entirely.

This analysis offers a tantalizing explanation for the motivations of some private firms to publish DNA sequence information as a way of forestalling patent claims, although in the end it is open to question how successful this strategy will be. The explanation is tantalizing because it is consistent with the observation that it is often the laggards rather than the leaders in DNA sequencing races that sing the praises of the public domain. Thus, for example, when Merck decided to sponsor the Merck Genome Initiative to generate partial cDNA sequences (expressed sequence tags or ESTs) in the public domain, two other private firms already had a significant lead over the Merck-sponsored effort in generating private databases of ESTs. Merck undoubtedly hoped at a minimum to create a set of unpatented ESTs that would be freely available without requiring a license from these firms. It is also plausible that by putting ESTs in the public domain, Merck hoped to create prior art that would defeat future patent claims to the full-length genes corresponding to the ESTs.[(27)]

The creation of patent-defeating prior art is an acknowledged part of the strategy of the SNP Consortium of private pharmaceutical firms and a private foundation that are paying for university-based efforts to identify points of variation in the human genome.[(28)] Again, the SNP Consortium entered the race late, after numerous other SNP discovery efforts in the private sector were well under way. Under these circumstances, patent-defeating publication may be their best hope retain their future ability to make use of information that would otherwise become proprietary. But if the patent-defeating goal dominates the goal of prompt dissemination of information, prompt publication in the public domain may not be the best way to proceed.

In fact, the SNP Consortium, in contrast to the Merck Genome Initiative and participants in the Human Genome Project that comply with the Bermuda Rules, does not publish all of its information as quickly as possible. Instead, it pursues a delayed publication strategy through use of the patent law instrument of Statutory Invention Registrations or SIRs.[(29)] The SNP Consortium candidly describes its intellectual property strategy on its web page as follows:

"The overall IP objective is to maximize the number of SNPs the [sic] (1) enter the public domain at the earliest possible date, and (2) to be free of third-party encumbrances such that the map can be used by all without financial or other IP obligations. To meet objective (2), the TSC intends to withhold public release of identified SNPs until mapping has been achieved to prevent facilitating the patenting of the same SNPs by third parties. Mapped SNPs will be publicly released quarterly, approximately one quarter after they are identified. *The intellectual property plan is intended to maintain the priority dates of discovery of the unmapped SNPs during the period between identification and release, for use as 'prior art*'."[(30)]

The mechanism for creating prior art prior to the date of public release of the SNPs is to disclose the information in a patent application that is subsequently converted to a SIR. This mechanism, which was added to the patent statute in 1984,[(31)] is codified at § 157 of the Patent Act. This statutory provision authorizes the Commissioner of Patents to publish without examination a statutory invention registration that that meets the disclosure requirements of the patent statute if the applicant waives the right to receive a patent on the invention within a specified period of time. A SIR has the "attributes specified for patents," but does not include the right to exclude others from making, using, selling or importing the invention. Among the defensive attributes of a patent that a SIR apparently has is that it is effective as prior art as of its filing date,[(32)] even though it might not be published for some time thereafter. In other words, it is possible to file a patent application that discloses a discovery, wait as long as the Commissioner will permit before converting it to a SIR, and then have the SIR count as prior art as of its filing date, just as if the disclosure had been published on that date. This permits the creation of patent-defeating prior art while deferring disclosure. In order to understand why this strategy for prior art creation might be preferable to prompt publication in the public domain, it is necessary to consider the disadvantages of releasing information in the public domain.

Reasons for Withholding Research Results from the Public Domain

Institutions in both the public and private sectors may have compelling reasons for withholding research results from the public domain. How these reasons are balanced against the reasons for making disclosure will vary depending on the priorities of the institution.

Retain exclusive access for paying customers. An obvious reason to withhold commercially valuable information from public disclosure is to preserve the power to sell access to the information to paying customers. It's hard to sell people something that they can get for free. DNA sequencing firms such as Incyte Pharmaceuticals and Human Genome Sciences that seek to profit from selling access to proprietary databases are thus understandably reticent to give the same information away for free. One would expect a similar concern to give Celera Genomics pause about fulfilling its promise to make the raw DNA sequence of the human genome available for free to scientists. But it is sometimes possible to sell proprietary access to information that is freely available in the public domain, so long as the proprietary product offers some value-added over the public domain version. Celera's paying customers are gaining access to sequence information before the public-release version becomes available, and the paying customers also get the benefits of annotations and proprietary bioinformatics capabilities that will not be released in the public domain.

Avoid disclosure to rivals. Another reason to withhold information from publication is that public disclosure lets your rivals know exactly what you have accomplished and

gives them the benefit of what you have learned so far. This can be a problem for both public/academic and private sector investigators and institutions involved in rivalrous research efforts, and seems to be a concern on both sides of the race to complete the human genome sequence. Celera has cited concern that competitors will repackage their data and sell it in competition with them in justification of contemplated restrictions on use of the "free" version of the human genome sequence that they have promised to make available upon completion.[33] The public sponsors of the Human Genome Project have been equally worried about Celera's use of the information that they are making freely available under the Bermuda rules. For example, when Celera recently announced by press release that they had sequenced 90% of the human genome, many people identified with public sector sequencing efforts found it galling that they included in that number DNA sequence data that Celera got from the publicly accessible depositary for sequence information from the Human Genome Project, Genbank. Apparently, representatives of the Human Genome Project are especially indignant that Celera's publications relating to the completion of the human genome sequence might include data deposited in Genbank by academic investigators who would not be included as coauthors.[34]

In a rivalrous race to accumulate information, everything you disclose in the public domain becomes available to your rivals and helps them get ahead. If one side makes their data freely available and the other side keeps their data secret, the rival that relies on secrecy will always know at least as much as the rival that makes prompt disclosures of all data. Sometimes, information disclosures will be of more value to the secretive rival than they are to the disclosing rival because of the cumulative value of combining the public data with the private data. Suppose, for example, that two rivals, Public University and Private Company, each sequences different portions of the same gene. Suppose further that the patent system offers more generous protection for full-length genes than for gene fragments. If Public University freely discloses its portion of the gene in Genbank, Private Company might add that information to the partial sequence it already has, quickly complete the sequence for the full-length gene, and file a patent application that it would not have been in a position to file without the Public University disclosure. Prompt disclosure in the public domain can thus be treacherous if your ultimate goal is to keep the information freely available. On one hand, public disclosure creates potentially patent-defeating prior art. On the other hand, it may enhance the value of complementary private information and even contribute to patent disclosures that will make it easier for rivals to get patents.

The SNP Consortium tries to limit this problem through a deferred disclosure strategy that uses the patent law mechanism of a SIR to create patent-defeating prior art as of an earlier date than it makes public disclosures that enrich the information base available to its rivals.

This is an interesting tactical variation on prompt public disclosure for institutions that are primarily interested in defeating the patent claims of others. Although the SNP Consortium has promised to make the DNA sequence variations that they discover freely available in the public domain, they are not simply putting the information up on a

website as soon as they identify it. Instead, they are filing patent applications that they plan to convert to SIRs.

Filing patent applications is as good as publication from the standpoint of creating patent-defeating prior art, but it's better from other perspectives. For one thing, by filing patent applications instead of posting or publishing their newly identified SNPs, the SNP Consortium avoids adding to the proprietary SNPs collections of their rivals. Whatever gets publicly disclosed will surely be added instantaneously to the proprietary SNPs collections to make them more complete. The SIR strategy also allows the Consortium to conceal from its proprietary rivals just what it has accomplished so far, creating uncertainty as to which of the SNPs that the rivals identify are worth patenting and which are already in the prior art. This imposes added patenting costs and may call into question whether patenting is worthwhile. On the other hand, the SIR strategy does not make as much information available to the research community as quickly as publication on a website would do. This may leave more people who seek prompt access to SNPs with nowhere to turn but proprietary collections. But since the SIR strategy promises eventual disclosure, those institutions whose needs for SNPs are less urgent may be content to wait, knowing that they will be freely available soon. Delayed access may be good enough for some of the pharmaceutical firms in the SNP Consortium who hope to use SNPs in pharmacogenomic applications that are years away. It may be less satisfactory for researchers who want to use SNPs to find genes.

Preserving Patent Rights. A final reason for deferring disclosure of DNA sequence information is to preserve the possibility of obtaining viable patent rights in the future. This concern may motivate institutions in both the public and private sectors to defer publication in precisely the circumstances that it might motivate other institutions to make prompt disclosure, depending on whether they believe that preventing the issuance of future patents is a good thing or a bad thing. Researchers who publish patentable research results without first filing patent applications thereby forfeit their patent rights in most of the world. Publication of results that have not yet ripened into a patentable invention may create patent-defeating prior art that would prevent the future patenting of more mature research results.

Apart from a concern about preserving their own patent rights, public research sponsors and publicly-funded research performers may worry that premature public disclosure may prevent them from complying with their mandate under the Bayh-Dole Act to patent research results in the interest of promoting technology transfer and product development. Indeed, this concern was cited by former NIH Director Bernadine Healy in support of NIH's decision to file patent applications on the first ESTs identified by Craig Venter before he left NIH.[(35)]

In fact, it does not appear that publication of raw genomic DNA sequence in the public domain will prevent the issuance of patents on genes that are subsequently found to lie within that disclosed sequence. Scientists estimate that expressed genes account for less than 3% of the human genome and are scattered across the genome in discontinuous stretches. Although the patent system has not yet resolved many of the legal issues that

will determine what portions of the human genome may be patented, for the time being there appears to be little threat that the disclosure of the human genome in the public domain will leave future researchers who identify and characterize genes with nothing left to patent.

In sum, complex strategies for endowing the public domain are at work in the field of genomics. These strategies arise out of the different plans of different institutions for extracting value out of genomic information, and are further complicated by the interplay of the public domain with the patent system.

1. © 2000 Rebecca S. Eisenberg

2. † Robert & Barbara Luciano Professor of Law, University of Michigan Law School. This research has been supported by a grant from the U.S. Department of Energy.

3. Eliot Marshall, *Talks of Public-Private Deal End in* Acrimony, 287 Science 1723 (Mar. 10, 2000); Public-Private *Gene Coalition Unglued*, New York Times, March 6, 2000 (Reuters); Justin Gillis, *Gene-Mapping Controversy Escalates*, Washington Post, March 7, 2000 at E01.

4. As quoted in Peter G. Gosselin & Paul Jacobs, *Clinton, Blair to Back Access to Genetic Code: The Two Leaders Plan to Issue Joint Statement That Data on Human Genome Should Be Public, Not Private, Property*, Los Angeles Times, March 14, 2000, Home Edition at C1.

5. Robert Langreth & Ralph T. King Jr., *Biotechnology, Genomics Stocks Plunge on Fear U.S. May Curb Gene-Data Sales*, The Wall Street Journal, March 15, 2000, at A3; Alex Berenson & Nicholas Wade, *Frantic Sell-Off Hits Gene Stocks*, The New York Times, March 15, 2000 at A1.

6. Robert Langreth & Ralph T. King Jr., *Drug Makers Offer to Assist Government's Genome Project*, The Wall Street Journal, March 14, 2000, at B6; Tim Friend, *Feds may have tried to bend law for gene map: Health agency denies any 'conspiracy' to recruit biotech company in race to finish project*

, USA Today, March 13, 2000, at 7A.

7. See J. Craig Venter, *Clinton and Blair Shouldn't Destroy Our Research*, The Wall Street Journal, March 21, 2000 at A26.

8. Robert Langreth & Bob Davis, *Sharp Drop in Biotech Stocks Is Linked to Bungled White House Press Briefing*, The Wall Street Journal, March 16, 2000, at A10.

9. See Rebecca S. Eisenberg, *Intellectual Property at the Public-Private Divide: The Case of Large-Scale cDNA Sequencing* 3 U. Chi. L.S. Roundtable 557 (1996).

10. For a description of the SNP Consortium, visit its website at http://snp.cshl.org.

11. Tim Friend, *supra* note .

12. See, e.g., Bloomberg News, *Genetic team fighting biotech costs, too*, The News and Observer (Raleigh, NC), April 16, 1999 at D2

13. See, e.g., *id.* ("Federal officials and a British charity secretly attempted to enlist biotechnology firm Incyte Pharmaceuticals in a race to complete the Human Genome Project and win a bitter two-year battle against another company, Celera Genomics of Rockville, Md."); Peter G. Gosselin & Paul Jacobs, *supra* note ("This month, ... the SNP Consortium agreed to underwrite a new approach to identifying as many as 1 million of the genetic variations using a method that would also help the publicly funded Human Genome Project close gaps in its detailed map of the genome. Celera suggested that this was simply a way for the genome project to beat Celera and throw business to rival Incyte,"); *Clinton/Blair statement on genome access sparks fallout in genomics sector*, Marketletter (Mar. 20, 2000)("[T]he Consortium has been in negotiation with the Human Genome Project to offer assistance in completing the latter's sequencing effort. Craig Venter, Celera's president, told the Wall Street Journal that he was disturbed by the news, saying it represents an effort by the public project to use corporate money to finish an assembled map of the genome before Celera does."); Lee Silver, *Who Owns the Human Genome?* The New York Times, March 16, 2000 at A31 ("[D]espite the high-minded rhetoric of the top academic scientists in the genome effort, a number of them have financial stakes in companies that are not mapping the genome themselves but hope eventuallyt to profit from the information generated by both the private and public efforts ...the many pharmaceutical and biotech companies that are not mapping the genome do not want to pay for either the raw genome data or the ability to understand it.")

14. J. Craig Venter, Mark D. Adams, Granger G. Sutton, Anthony R. Kerlavage, Hamilton O. Smith, & Michael Hunkapiller, *Shotgun Sequencing of the Human Genome*, 280 Science 1540 (1998).

15. Initially, Celera's founders promised release of raw sequence data on a quarterly basis. More recently, Celera founder and president J. Craig Venter stated in the Wall Street Journal that "Celera stated from its formation that it would publish the human genome sequence when it was complete. We still intend to do so." J. Craig Venter, *Clinton and Blair Shouldn't Desroy Our Research*, *supra* note .

16. *NHGRI Policy on Release of Human Genomic Sequence Data*, posted on the internet at http://www.

17. Ralph T. King Jr., *Code Green: Gene Quest Will Bring Glory to Some; Incyte Will Stick With Cash*, The Wall Street Journal, Feb. 2000, at A1.

18. See Rebecca S. Eisenberg, *Public Research and Private Development*, U. Va. L. Rev.

19. See R. Waterston & J.E. Sulston, *The Human Genome Project: Reaching the Finish Line*, 287 Science 53 (1998); Nicholas Wade, *The Genome's Combative Entrepreneur*, The New York Times, May 18, 1999 at D1.

20. See Nicholas Wade, *10 Drug Makers Join in Drive to Find Diseases' Genetic Roots*, The New York Times, April 15, 1999 at A27.

21. See generally Rebecca S. Eisenberg, *Intellectual Property at the Public-Private Divide: The Case of Large-Scale cDNA Sequencing*, 3 U. Chi. L. S. Roundtable 557, 569-71 (1996) (discussing why Merck was willing to sponsor an effort to put cDNA sequence information in the public domain).

22. The Bermuda rules, which require publicly-funded investigators to deposit all newly identified DNA sequences and mutations in the publicly-accessible GenBank database within 24 hours, derive their name from an agreement entered into at the International Strategy Meeting on Human Genome Sequencing held in Bermuda in 1996. David R. Bentley, *Genomic Sequence Information Should Be Released Immediately and Freely in the Public Domain*, 274 Science 5287 (1996). The Bermuda rules have been criticized as promoting public disclosure of data that have not been checked for accuracy. Mark D. Adams & J. Craig Venter, *Should Non-Peer-Reviewed Raw DNA Sequence Data Release Be Forced on the Scientific Community?* 274 Science 534 (1996).

23. Of course, prompt deposit of sequence information in the public domain can readily be justified as a way of giving the scientific community the benefit of free access to as much sequence as possible as quickly as possible, without invoking an anti-patent motivation. The Bermuda rules are not the only evidence of an anti-patenting norm for raw DNA sequence information within the Human Genome Project. See National Human Genome Research Institute, *Policy on Availability and Patenting of Human Genomic DNA Sequence Produced by NHGRI Pilot Projects*, April 9, 1996, posted on the internet at
http://www.nhgri.nih.gov/Grant_info/Funding/Statements/RFA/intellectual_property.html.("In NHGRI s opinion, raw human genomic DNA sequence, in the absence of additional demonstrated biological information, lacks demonstrated specific utility and therefore is an inappropriate material for patent filing. NIH is concerned that patent applications on large blocks of primary human genomic DNA sequence could have a chilling effect on the development of future inventions of useful products....The grantees are reminded that the grantee institution is required to disclose each subject invention to the Federal Agency providing research funds within two months after the inventor discloses it in writing to grantee institution personnel responsible for patent matters. NHGRI will monitor grantee activity in this area to learn whether or not attempts are being made to patent large blocks of primary human genomic DNA sequence.")

24. 35 U.S.C. § 102.

25. 35 U.S.C. § 103.

26. Gideon Parchomovsky, *Publish or Perish*, 98 Mich. L. Rev. (2000).

27. Although the issue is not entirely free from doubt, it now seems unlikely that publication of an EST in the prior art would make the corresponding full-length gene obvious as that standard has been applied to claims to DNA sequences. See In re Bell, In re Deuel.

28. http://snp.cshl.org/about/program/html

29. 35 U.S.C. § 157

30. SNP Consortium website (last visited March 14, 2000) (emphasis added).

31. Pub. L. No. 98-622, § 102.

32. The basis for asserting prior art status for a SIR as of its filing date is the language of § 102(e) of the Patent Act, which precludes issuance of a patent on an invention that was "described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent." For an analysis of whether prior art status as of its filing date is among the "attributes" of a patent to which a SIR is entitled, see Chisum on Patents at § 3.07[2].

33. See J. Craig Venter, *Clinton and Blair Shouldn't Destroy Our Research*, *supra* note .

34. Eliot Marshall, *Talks of Public-Private Deal End in Acrimony*, 287 Science 1723 (2000).

35. Adler, Healy articles about NIH Venter patent filings.