

Exploration for Intellectual Capital – Legal, Technical and Social Issues
Autism – A Mystery of Epidemic Proportions
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Introduction and Overview:

This study started as an exercise to determine the feasibility of finding new technology development opportunities by scouring the internet and inventorying the underlying legal and technology assessment issues affecting technology transfer programs, particularly within academic institutions. It represents a shift in focus from the conventional technology transfer paradigms which appear to address mature intellectual capital. The underlying premise of the exercise is that intellectual capital, the new wealth of nations, can be identified by using search technologies on the internet. Academic institutional players are arriving in increasing number to the technology transfer party. The proven tradition of entrepreneurs in other fields has always been to find new sources of opportunity designed to avoid direct competition with established players in the market.

The project assumed a second dimension when the early decision was made to focus on autism causation as a subject with enormous social and economic potential. As will be noted during the course of using autism as a study focus, the sheer volume of grants, funded projects, anecdotal reports, clinical studies and CDC characterization of autism as “epidemic,” assured more than adequate material for internet search and mining.

The overall exercise raises questions that “tweaked” the curiosity gremlin¹ and at this stage the focus has been primarily of identifying questions for further study rather than definitive answers.

This project presentation thus represents a “first look” at an ongoing study directed at mapping issues encountered along the road relative to creative search for new sources of intellectual capital. The issues identified are, for the most part, ordinary, repetitive and obvious. However, even though every intellectual property scholar will see them as obvious in terms of “rules,” in the context of making decisions regarding risk assessment judgments in the use of what is believe appropriate, the questions assume a slightly different character. Likewise, factors affecting access to facts, ideas and internet publications which can properly be used for further development also assume increased significance and possible redress of the balance in protecting property rights with the public interest, particularly as reflected in public health, safety and welfare requirements.

¹ On occasion, when the moon and the stars are in special alignment, pangs of curiosity result in esoteric inquiries. In this instance, the inquiry involves seemingly disparate elements. This may be one of those celestial undertakings to follow a different path to perform tasks the outcomes of which will most like not be realized at the end of the excursion, but potentially have value to the next traveler.

The study was organized along the following lines:

First, evaluate the best methods and sources, as well as the utility of search technologies to “mine” information structures and filter potential opportunities for appropriate technology seeding, cultivation and development.

Second, consider the dependent variables that affect the information availability. Availability for information sharing includes (1) digitalization (2) posting on the internet (3) access to the host server and posted materials and (4) the right and/or ability to use the appropriate elements under existing property and intellectual property regimes.

Third, to include the tools for identifying and linking to appropriate materials, which are in turn dependent on search engine design and capabilities under law. Inherent in the search variables are limitations that underlie existing property and intellectual property regimes. These issues are themselves related to (1) property rights that permit exclusion and control of use and (2) issues surrounding the appropriate assessment of rights of use involving “facts,” “ideas,” “function,” and matter not the subject of copyright or patent protection. Both of these, in turn, involve reasoned assessment of opportunity and “risk management.”

Fourth, based on the information obtained in the initial search, seek to develop a test project proposal including a working hypothesis and reasonable description. Describe the project in sufficient detail to permit a preliminary review of essential elements using available published data. Modify the search to include new data and modify the project description and goals according.

Finally, conduct a broad search on essential terms and conditions as necessary to empirically or scientifically validate the essential foundations of the proposal with due regard to issues of property and intellectual property regarding publications of data and access thereto.

As part of each stage of the exercise, identify and describe the social, economic and legal issues that can be anticipated to apply specifically and generally in the creative process of mining for intellectual opportunities.

Section I – The Test Project Formulation:

A. Some Basics in Formulation:

As noted above, the project was redirected to identify subject matter that had significant sets of public issues. This was to ensure there would be adequate material available on line. The early assessment identified several medical issues by the use of search engines. In the process, a number of threshold questions were raised about the tools of search and limitations on availability of information and access to web sites or data sets.

1. Search Engine Standards of Relevancy and Order

This first search identified the obvious fact that search engines are not held to a universal standard of relevancy and reporting. Search engines are at the core of business ventures that earn substantial revenues through advertising revenues, or the sale of reprioritizing the order of “links.” The majority of search engines represented by Google, Yahoo, Dogpile, Hotbot earn their revenues by click through activities, or prioritization of place in the reporting order. Search engines have also become an integral component in related online services which themselves collect data about user activities. Google is a prime example of this extended model as it collect and maintains relational data involving actives from its’ freeware, such as Gmail, Picasa and other services. While Google clearly serves an important public purpose, it is a private enterprise serving its own primary business private ends. This observation states the obvious that search results are shaped by the private rights of the search engine proprietor, further compounding the already difficult task of resolving fair use for permissive public purpose.²

Repeated searches using different words and the misspelling a key word (such as vaccine) leads to a different ordering of response. Whether this means that the search engine is compromises/flawed, or that there should be rules requiring neutral returns is a separate question. The fact is that Google’s property rights affect the outcome, or may impose a collateral cost in efficiency on the search.³

This observation, in the context of the exercise, led to a conscious change in perspective regarding the assumed functionality of digital information structures and raised questions whether there should be some minimal standards established for ordering and reporting.

2. Invisibility

The prospect of invisibility constitutes another limitation that affects full functionality of the internet information infrastructure. Intellectual property rights permit content right holder to make both their web sites and information invisible to the end user because the search engine web crawler must respect that elements on the internet may be

² See e.g., *Perfect 10 v. Google, Inc.*, 416 F.Supp.2d 828 (U.S.D.C. C.D. Cal. 2006); *Perfect 10, Inc. v. Amazon.Com, Inc.*, F.3d , 207 WL 1428632 (C.A. 9th cir. 2007).

³ See generally case challenging Google’s change of position in response to query and the selling of adwords: *Rescuecom Corp. v. Google, Inc.*, 456 F.Supp.2d 393 (N.D.N.Y.,2006). See also, <http://www.phptr.com/articles/article.asp?p=607376&seqNum=6&rl=1>. And, Niva Elkin-Koren, "Let the Crawlers Crawl: On Virtual Gatekeepers and the Right To Exclude Indexing," 26 *University of Dayton Law Review* 179, 188 (2001; and, the attempt to have a neutral search engine without bias. This public purpose issues are reflected in: http://news.com.com/Project+searches+for+open-source+niche/2100-1032_3-5064913.html. A web site purporting to be a guide to search engines can be found at: <http://www.searchengineguide.com/?gclid=CNCDt6ehtf0CFSgRGgodbG0Z1A>

excluded and therefore not “visible” to the end user of a search engine crawler because the content “owner” has the power to “opt out.”⁴

3. Evolving Search Capabilities and Gnomes

It isn’t clear how far or fast search engines will evolve in the future, or what public policies in the public interest may ameliorate the limitations imposed by intellectual property rights. The majority of issues appear to be in the rapidly developing capabilities of search paradigms with artificial intelligence capabilities. A search using “Auto Grnome,” an artificial intelligence search engine and web crawler that has the power to learn from searches that are conducted and mimic the user, can automatically continue to search based on the original and modified search. In looking for information on the ultimate subject project, it showed not only the specific direction of research on autism, but concentrations of research projects being conducted relative to autism globally. It continues to crawl on the web looking for data that matches the search which can be accessed at any time. Anyone who has conducted an extensive search can appreciate the repetitiveness of the search and the burden of reviewing all material identified. The ability to harness the potential of web crawlers significantly alters the time frame of the search by rendering the task persistent and tireless.

4. Access, “Terms and Conditions” and Limitations on Use

“Access” and “availability” issues noted in early searches unquestionably limited information on web sites from being access or used. First, access to a web site requires compliance and agreement with the terms and conditions set forth by the server or content provider. These terms and conditions potentially express limitations on use that restate or exceed intellectual property rights that under copyright or patent law.

Second, the extent to which identified relevant sites had locked doors to general access was not fully expected. That is to say, the door was often closed and access denied reviewing of content, whether protected by intellectual property, or otherwise as unprotected materials. Even where access to the site was granted, the terms of use and express site limitations were included to protect the legitimate proprietary interests of the site and/or server “owner.” These restrictions involve limitations on access without registering and/or signing in, requirements for joining an organization or paying a fee for “membership,” or, having initial access limited to abstracts of papers or other documents, with access to the full document dependent on payment for purchase or view. Each of these provided obstacles, albeit not unreasonable, nor insurmountable, in the search for facts, ideas and other unprotected elements of both copyright and patent regimes that could be used as the seeds for intellectual capital.

⁴ See e.g., *Perfect 10 v. Google, Inc.*, 416 F.Supp.2d 828 (U.S.D.C. C.D. Cal. 2006); and, *Blake A. Field v. Google, Inc.*, 412 F. Supp.2d 1106 (U.S.D.C. D. Nevada, 2006).

5. The Grey Area of “Facts” and “Ideas”

Third, while “everyone knows” facts and ideas are not copyrightable, are you sure what you access and use is an unprotected idea or fact? How sure are you? And, if there is any ambiguity, what is the cost in time and money of proving you are right. Does *Feist Publications v. Rural Telephone Service Company, Inc.*, 499 72 U.S. 340, 111 S.Ct. 1282 (1991), or, *CDN, Inc. v. Kapes*, 197 F. 3d 1256 (9th Cir. 1999), or any number of hundreds of other cases involving “alleged” facts or ideas address the perspective of looking for opportunities? Consider, by way of example, Dan Brown’s multiple litigations in the United States (*Brown v. Perdue*, 177 Fed.Appx. 121, 2006 WL 1026098 (C.A.2 (N.Y.)(2006)) and England (*Baigent v. Random House Group Ltd.*, 2006 WL 1020604 (Ch D 2006)) regarding the DaVinci Code. What were the costs of those litigations? Brown admittedly read Baigent and Leigh’s book, “The Holy Blood and the Holy Grail” and probably used facts and ideas, but not expression from them, neither of which are protected elements. This did not stop the litigations. What this represents is a question of “risk management” which should not be overlooked when considering “use” of materials not thought protected by intellectual property in a global economy where intellectual capital is “golden.”

6. Transaction Costs: Risk Assessments Fair Use - Derivative Rights

Finally, on the subject of use of ideas and facts in the context of copyright, one has to account for the costs associated with “fair use” as a “defense” and an apparently expanding sense of inclusion when it comes to considering matter “derivative.” The assumption tested by the project is that by reviewing facts and ideas that could be used as building blocks, new or alternative direction could be created. This is particularly appropriate where prior models had failed, or left room for improved or differential design opportunities. These are issues that raise questions regarding “risk assessment.” From the perspective of this project looking for materials in the public domain to work with as element or catalyst for intellectual capital opportunity uncertainty becomes a calculated risk with the potential of enormous transaction cost.

7. Autism: A Project Meeting Readiness Assessment

At the outset of the quest for opportunities, indicators pointed to Autism as an issue of “epidemic proportion” more than worthy of attention. A requisite element in any market engagement is that of market readiness assessment and instances involving epidemics need no further market readiness validation. Nor, was there likely a dearth of information relative to current research, hypotheses, speculation and conjecture within the medical profession and amongst the general populations. The project was redirected to reviewing current study, assessing prevailing research concentrations and questioning whether there were indications of success, or proof evidenced in existing study directions. If not, then informed of what it was possibly “not,” to work with ideas, facts and materials noted during the threshold survey to develop alternatives paradigms addressing causation, however outlandish at first blush. This was structured around identification of

common denominators, as well as notable and discrete differences in time frame, numbers, and concentrations of occurrence, global or local, genetic, environmental, catalysts, better diagnosis and medical, as well as any number of normal threshold questions that everyone would ask.

B. Ergo: The Draft Assignment:

Exploration and Mining for Intellectual Capital Autism – A Mystery of Epidemic Proportions March 2007

This project challenges portions of conventional process in the identification, readiness assessment, and capture as steps in bringing to market intellectual capital. It would appear that opportunities present themselves through more or less conventional formats and contexts. They inhere in the usual places: industry research and development departments, university research (funded and non-funded) and entrepreneurial activities that either has directed or incidental results of intellectual value. In some ways, this may be perceived as intellectual identification and capture of ideas early in the maturation process, but birthed to the extent that they are identifiable. This project assumes, or postulates, that there is a universe that precedes this which can be cultivated to satisfy user identified needs. It is a universe where the seeds may need cultivation or never come to a point they can be identified or mature into otherwise ripe intellectual content.

Likewise, the conventional wisdom supports research for known needs, but it does so in places that have proven histories of productive research capabilities based on personnel, institutional and other factors tending to provide the essential ingredients of success.

This project asks a set of questions which require some thought as to how one might find the seeds for cultivation. How one might structure questions and searches unbounded by conventional sources to find and evaluate the potential for these seeds in their current place or in more fertile grounds. It asks what degree of remoteness from the central focus or purpose of the inquiry will be tolerated in initiating an interest regarding something which does not appear relevant, reliable, of interest to existing scholars, researchers or scientists. Assuming 99.9% as a rejection rate, is the possibility of .1% sufficient to warrant the search? Since the likelihood of finding something of value is so slight, will we be able to capture something from the search itself to improve our techniques or direction?

What protocols are needed to ensure the widest search possible? What legal (proprietary) barriers might there be that close the search path, when and how might they be opened and what legal issues or “crafting” might open the doors and permit subsequent use of data and ideas?

Are these issues any different than finding more readily identifiable matter of intellectual value, capturing (privatizing) with appropriate proprietary coloring, structuring manufacturing and marketing agreements and bringing it all to fruition and market? What institutional or individual biases need be addressed?

This exercise starts at that first level. The search has to be structured and verbalized to indicate what indicators might justify further interest. What does one do if they see something that could morph or be channeled in a direction that might respond to user needs that has been identified?

The Autism Epidemic

What does it take to become epidemic? What makes this topic different? Here is an illness that appears to have no bounds, no direct link to place or time, which has all the characteristics of being ubiquitous. Yet, the statistics that follow, along with the questions posed indicate that autism does have anomalies in special differentiation. Can that difference be significant? The CDC notes that one out of every one hundred sixty children is autistic (1/160). This value changes dramatically for New Jersey where the statistic is one child in every fifty is autistic (1/50). Does this mean it is epidemic? Does this mean it is a national problem? Does this mean something has changed? Does this mean that it wasn't always so? Does this mean that change has occurred over time, or that it is sudden? Does this imply genetic changes or environmental changes affecting both the parent and the child? Could it be something that is mutagenic and changing basic structures? Could it simply be classification, or identification, or diagnostic advances? Could it be prenatal diet, chemicals, exercise (or lack thereof) or changing age patterns of birthing? Could it be the birthing process itself? And, how does each of these questions fit into the determination whether the difference in New Jersey reflects an anomaly that may help in the search for the cause of autism?

Where do you start? Do you start with a review of conventional medical or research literature? Do you start with the news? Do you use tools and search engines that are available? What and how you structure your search through anything that can be searched?

This simple search indicates the bounty of non-juried search structures. A recent search for DVT (Deep Vein Thrombosis aka blood clots – not epidemic yet because only 100,000 die each year from Pulmonary Embolisms) in the medical literature didn't yield much by way of remediation, just treatment and a prognosis of dependency on blood thinning medications. A search using the more popular generic search engines produced cause, frequency, statistical data regarding how, what and when, immediate consequences of early diagnosis and treatment, preventive steps and confirmation that conventional medical responses had not move far along the path of reversal. Interesting, those who aggressively and often engaged in athletic endeavors, such as triathlons, or marathons were the most

likely to get blood clots and then DVT when getting on an airplane after exercise. And, these were persons aware of their bodies, yet not familiar with obvious symptoms of trouble. Where was this information found, in running journals, health magazines, news articles reporting on the death of a local athlete?

For the purpose of this exercise the class will be divided into two teams. The end result would be perfect if one could identify “the” seed that would lead to a resolution of autism, but we will set the standard for success when we find out what can be determined by your searches. The search can include internet chatter, established research, public documents, and materials from the CDC, medical publications, forums, blogs and the like.

1. Scour the literature and news to identify possible sources of information regarding autism.
2. Review all data relevant to the extent and nature of problems and study protocols.
3. What are the concentrations of research, premise, study and what might be a quick assessment of current stages of success, proof or change in direction?

These set the stage to explore further in the formation of a study paradigm for mining - trace elements or fertile ground. How we define the indicators, what boundaries exist, what we can't get access to even by way of indicator and what legal issues can be identified are all relevant.

The operating premise is that innovation, invention and genius are often user driven.

If nothing else, these exercises may also help us understand the practical and legal issues confronting technology development from different perspectives.

Section II –Few Expectations, Unexpected Outcomes:

A. Discussion and Search Activities Specifically Autism

The first task at hand involved a series of shared searches on the internet, using a number of different readily available search engines, such as Yahoo, Google, Dogpile and hotbot, among others. The expected list of questions used in the initial search involving autism was to identify:

1. Who is researching?
2. What and why as indicated in their research?
3. Are there any/many reported successes?
4. Are they simply barking up the wrong tree and wrong?

5. On noting the number of repetitive/similar research – why?

The list of areas in which research appeared to be concentrated included:

1. Vaccinations
2. Genetic Markers
3. Genes and hereditary issues
4. Environmental Non-Specific issues
5. Pesticides
6. Air Quality (regional)
7. Air Quality (domestic)
8. Food additives
9. Water supplies
10. Virus

Each of these study areas apparently held sufficient promise thereby justifying the appearance of significantly large concentrations of grants and ongoing research in sponsoring institutions. The fact that so many research ventures appear to be funded for similar research purposes could be taken to validate the directions under scrutiny, albeit the fact that these areas are funded may beget the applications themselves. This slightly jaded or cynical observation may be blamed on the absence of any firm indications of the cause or causes autism. It buttressed the development of the hypothesis and project that follow with the startling premise that existing directions are “wrong,” and that any new premise could be “right.”

B. The New Hypothesis – Applied Systems Analysis

As part of the group discussion, Dr. Yohann Sulaiman, Ph.D., a systems analyst and third year law student (Spring 2007), presented his perspective approach to autism to a highly skeptical audience of eleven classmates in a technology transfer seminar. The group consisted of students, most of whom had advanced degrees, some in the sciences, including biology, chemistry and engineering. Many of these students were interns, or worked for the University at Buffalo Technology Center, called STORRS. Several members of the class were admitted to the patent bar.

The theory that follows reflects both the conversation in class and subsequent infusion of thoughts generated by that presentation.

C. An Autism Causation Theory:

The preliminary search and review of studies indicate conflicting and inconclusive theories, as well as a lack of general agreement on the cause (or causes) of autism. This is a work in progress with a number of caveats, including the important reminder that the hypothesis was developed to test the functionality of internet search capabilities in the context of intellectual property rights. The statement that everyone else is wrong and that we are right, or heading in the proper direction, is “for hypothesis

testing only,” clearly a beta enterprise. On the other hand, the causes of autism may well, as our searches indicate, be attributable to a set of factors and the hypothesis may constitute an essential and limiting or contributing factor as a cause of autism. As the project itself stated, the likelihood of finding an answer is generously stated to be somewhere in the .1% range – on the other hand, who is to say what is proposed may not be wrong, or point someone who can be right in a new direction?⁵

1. Everyone Thus Far is Wrong

The primary function of system analysis is to determine the cause of malfunction. When the expected failure rate of a process exceeds the established boundaries of acceptable limits, identifying the cause of failure is a necessity. If others have attempted to determine the cause of failure, the first and foremost lesson is to review their work. If no one can or has succeeded, that one may thus start with the statement, based on the lack of any conclusive research or proof to the contrary that “”everyone else thus far is wrong.” Of course, this is a little “tongue in cheek,” but for the purposes of this exercise one can reasonably assume that it not any of the current research on the list. This includes vaccinations and pesticides which are the subject of current legal action.⁶

2. The Subject is a Human Mammal

The subject matter under study is a human being. The nature of the disorder is evidenced by a learning (cognitive and social) disability, which depending on severity may be partially addressed through therapy.⁷ Humans are mammals and as such have characteristics similar to other mammals. It should be noted that a simple search using Westlaw produced over one thousand cases referencing autism, including several suits involving vaccinations and pesticide applications.)

3. Setting the Baselines for Deviation

The nature of acceptable failure rates and deviations from any norm are a necessary starting point. The first task, therefore, is to determine if there is a known base line or historic curve indicating an expected failure rate involving children that we describe as

⁵ Almost as an embarrassed aside, as this disclaimer is inserted, repeated searches show studies and data addressed at “oxygen” and early fetal development, or oxygen related therapies for remediation. A representative sampling in the following links - See e.g., Oxygen Deprivation May Contribute to Autism, Forbes: <http://www.forbes.com/lifestyle/health/feeds/hscout/2005/12/19/hscout529762.html>; Oxygen deprivation 'could be contributing cause of autism' – (Study of Rats): <http://www.autismconnect.org/news.asp?section=00010001&itemtype=news&id=5645>; Autistic Conjecture of the Day: <http://autisticconjectureoftheday.blogspot.com/2005/12/oxygen-deprivation.html>; Hyperbaric Oxygen Therapy (HBOT) adjunctive role in the treatment of Autism: <http://www.reimerhbo.com/autism.htm>.

⁶ The concentrations of and types of research in these areas should have already produced a positive result if the path were eminently correct.

⁷ <http://www.healing-arts.org/children/autism-overview.htm>)

autistic. The subject of the exercise as human is also a mammal. Is there any evidence of cognitive or social behavior that can be observed in other mammalian species? A deviation from a known normative curve applies to mammals as any other production system in the analysis and explanation of systems failure.

1. What historically was the deviation curve been for autistic children?
2. Has that curve changed?
3. If so when and then why?
 - a. Does the current number of cases labeled autism reflect an increase in the number and timing of professional health care visits, better diagnosis, or both?
 - b. Does the apparent rate change indicate a generalized lumping of similar generic ailments under one label?
 - c. Are there any identifiable exterior forces or factors?
 - d. Is there any identifiable indicator in the genetic, physiological or function of the fetus or child?
 - e. Is there data distinguishing occurrences based on distinct global areas, including nation states, regions or site specific occurrences?

4. Deviation and Failure Rate Mammals (Non-Human)

Are there incidents in history where mammals have been globally implicated by specific environmental changes?⁸

By asking the questions in this way, the current global involvement with autism as epidemic is appropriately given a scale that considers it “ubiquitous.” It further permits questions of whether and how different species might have had the ability to adapt, survive or return at a later date. If we are dealing with radiation, global warming, changes in oxygen or carbon dioxide levels as a factor in the autism causation calculation then the model needs to be expanded to include global factors.

What is ubiquitous? What could affect large populations? Has anything in history every affected entire species before? Has anything cause harm to mammals?

Changes affecting all mammals were noted at two points in time. First, during global cooling (The Ice Age) and second during the period when it is thought earth suffered a series of meteorites of massive proportion striking the surface. The meteorites so corrupted the air that reptiles and mammals became extinct. Was the air “poisoned?” Did oxygen and carbon dioxide levels change? Was the ability of mammals to adapt stressful or fatal? What happened to dinosaurs and were they able to adapt and if so why until the onset of the Cenozoic period 65 million years ago.

Has the incidence of autism spiked? If so, when was the dramatic increase first noted? Statistically, reports can be read to indicate that it occurred shortly after the

⁸ <http://darwin.bio.uci.edu/~sustain/bio65/lec02/b65lec02.htm>

global energy crisis in the 1970s. What factors might have changed in response to the energy crisis that could affect embryonic or early childhood development?

The theory posited is that after the energy crisis the following occurred:

- a. New Housing construction insulation standards and retro-insulation and upgrading of windows in existing housing.
- b. Diminished exchange of outside and inside air because windows kept closed and/or fresh air not exchanged in HAVC systems.
- c. Diminished oxygen levels and elevated carbon dioxide levels in “sealed” housing.
- d. Decrease in inhabitant/mother’s blood oxygen levels during pregnancy.
- e. The growth rate of babies during the early periods after conception is at its highest and a question is whether this can affect the child if the oxygen levels supplied during this extraordinary growth period is decreased. It was suggested that blood flow through the umbilical cord was limited by the interior dimension and which is not expandable.
- f. Brain growth and function occurs and can be affected during this period.
- g. This result is a learning disability of varying degree.
- h. The incidence of children diagnosed as autistic increases.

Is this hypothesis describing a coincidence, or is it describing a contributory or primary factor explaining the spike to epidemic proportions behind autism?

The restated hypothesis, therefore, is that because of the energy crisis in the early 1970s, new housing construction was held to a higher standard of insulation, windows, doors, heating and air-conditioning. That many households remained sealed during cold weather to avoid heating costs and that households with air-conditioning remained sealed during hot spells with air-conditioning rather than open windows. That, despite design and recommended standards, many furnaces did not use outside air for the furnace, but rather were set by the end user to re-circulate inside air to avoid the assumed expense of heating colder air. This in turn reduced the oxygen levels in houses and increased carbon dioxide levels, however slightly. This reduced oxygen level affected the fetus during early development and throughout the period of prenatal development. This is a cause or contribution factor in subsequent diagnosis of a child with autism.

Part IV – The Challenge of Testing Medical Hypothesis

A. Key Elements of Theory for scientific proof or empirical evidence:

The theory of oxygen deprivation during early embryo development involves a number of integral elements that need measurement, testing and verification. These include:

1. A measure of oxygen levels in sealed homes;
2. A determine the period of diminished oxygen during pregnancy;
3. Finding the date of birth and counting back nine months to determine if hot weather or cold weather;
4. Establishing by reference or other evidence that brain function is determined at early stages of embryonic development and list functions that would be included during this period:
 - (a) Eye sight and vision
 - (b) Motor processes
 - (c) Cognitive processes
5. Determining whether there are regional differences based on climate, lifestyles and standards of living;
6. Reviewing clinical programs and reports addressing remediation and characterizations of causes and affects including post diagnosis treatment of autistic children

B. Constraints on Testing Human Subjects - Fully Informed

a. Statute and Regulations

Current regulations require that any human subject be fully informed of the protocol and risks involved in the procedures being used.

These are set forth in the Code Federal Regulations, title 45 – Public Welfare, Part 46.

For a discussion of Federal Regulations requiring informed consent see generally:

(http://research.ucsb.edu/compliance/human_sbj_informed_consent.shtml)

Code Federal Regulations, title 45 – Public Welfare, Part 46
Protection of Human Subjects: Subpart A – Basic HHS Policy for
Protection of Human Research Subjects.

Subpart B – Additional protections for pregnant women.

b. Moral Issues:

For the most part these issues seem to center on medical use of Marijuana, abortion, stem cell research and the like. Ethical issues in medicine are distinct from moral issues. One can visualize this distinction with the use of Marijuana to alleviate pain for those who suffer from cancer, or the issues surrounding stem cell research for those who suffer from degenerative disease could be treated through stem cell protocols. Depending on the outcome of research concerning autism this could be an area where stem cell applications will confront the ethical treatment and moral judgment chiasm. (See generally and enlightening discussion in the context of medical research:

http://home.earthlink.net/~irbwatch/index_files/Shapiro.pdf)

c. Ethical:

These involve medical ethics in the treatment of patients.

<http://www.nihtraining.com/ohsr/site/guidelines/helsinki.html>)

The question, therefore, is who would suggest and who would consent to subjecting their child to the possibility of autism if fully informed of the working hypothesis?

It is this scenario of broad based data collection, relational search engines, non-invasive data collection that holds promise for an internet search needed to address the working hypothesis of this project.

1. Function of Internet empirical data and validation
2. Distinguishing scientific research and proof from threshold data collected during pregnancy.
3. The internet and search engine role in avoiding medical ethics, moral and invasiveness issues.
4. The internet presents innumerable opportunities to collect and collate data from diverse sources,
5. Clinical remediation practices and studies characterizing causes and affects as informing the issue of causation.
6. The list of internet and search engine issues noted in the original search, has to be expanded to consider relational data base potentials, Gnomes, artificial intelligence, privacy and due process issues and more.

IV. Thoughts, Futures, Data, Searches, Intellectual Property and What have we learned?

What have we learned about autism?

First, and possibly foremost, there is no single factor that has yet been identified as the cause of autism. New studies are focusing on the likelihood that autism is the result of a combination of factors, some of which may be enabling and others limiting, some physiological and other environmental. A number of studies are attempting to identify factors that would indicate both predisposition and incidence.

There is a significant body of data, but the data and clinical experience necessary to approach the articulated hypothesis, does not appear readily available through the use of present search protocols.

The missing factual data is critical as to the determination whether autism is on the increase, the time of change from prior levels, whether the hypothesized spike in incidence occurred in the early nineteen seventies (1970s). If nothing has changed, then facts are needed to determine whether the apparent increase in autism relates to more frequent medical treatment, better medical treatment and diagnoses of the existence of autism, more public awareness that leads to visits and diagnosis statistically showing higher number that don't necessarily relate to a larger number actually being autistic. If something has changed, how likely is it that it would be genetic after these thousands of years? If it is determined to result from an internal factor, is there an external catalyst? Finally, the question has to be addressed whether it was global or regional, whether there are regional differences that can be measures, whether there are habitation differences that can be determined and measured, whether these levels result in changes in oxygen/carbon dioxide levels in housing, whether there are other elements in the air of "sealed" housing, whether these levels existed from the onset and throughout pregnancy. There are, in fact, a growing number of proposed oxygen related therapies and some theories involving oxygen during pregnancy and at birth that don't show up until you specifically look for "oxygen" in the search.

What have we learned about Data, data base structures and utility, search engines Through the Autism Study?

1. The autism study requires a complex of basic and relational data not available presently because of one or more of the following factors:
 - a. The data is simply not digitalized
 - b. The data is not on line (possibly by choice not to share)
 - c. The data is on line, but not available because proprietary control over web access

1. The web proprietor has exercise "opt out" notice.

2. The web site or server imposes limitations on access to materials and data:
 - a. Membership
 - b. Registration
 - c. Charges for access
 - d. Charges for use
2. Many if, not most, searches are limited by public search engines and the manner of indexing and showing matching links.
3. Sophisticated search engines should be capable of the following:
 - a. Reporting all links with a published or understood prioritization
 - b. Accepting and reporting by aggregated searches including multiple links with the ability to assign weights to different included factors
 - c. Adopting neutral protocols for relational search with weighted links and responses.

4. Access to relational data not previously made available should be subject to rigorous standards and protections as noted below:

The amount of data that Google collects from varied sources including searches using search engine, email using Gmail, pictures using Picasa, “adware,” Google docs and spreadsheets, Google Desktop, Google Talk and Google Product Search constitutes a valuable public asset and unparalleled contemporary relational and persistent data base. See for example, Google: Is Google too powerful? *PC World August 2007* – pages 18-20

The potential represented by Google’s database should be taken into account as recording even the most casual conversation which may have relevance if made a part of an aggregation of data concerning exposure to environmental factors or other incidents occurring during pregnancy. This data may include speculation whether the child is autistic, symptoms and remediation, other members of family with similar symptoms or diagnosis, where one lives, when the child born, age of diagnosis. Obviously, the extent of personal information, threat to privacy and person, as well as due process issues affect the scope of this data, access and use. However, are there instances, such as those of “epidemic proportions,” that might justify controlled access to these data sets, much the same as one would find with “homeland security?” Google’s capabilities may simply be the model for future “mining” for data from single entities that collect data from multiple sources, or from unrelated in creating a relational data base.

5. Artificial intelligence and the use of Gnomes that learn and enhance search capabilities that can access open and relational data sources not only enhance, but will challenge existing property controls over content. The power of the Gnome to adapt based on search characteristics of the primary user can be understood by manually attempting distinct searches with slight differences in words or structure to note the results in return and utility. For example search using “autism causes.” Then search

using “autism oxygen.” And, finally search with the term “autism vaccination.” The differences are dramatic. A Gnome capable of adaptation using artificial intelligence would constantly change the search terms yielding the potential of a significantly enriched return.

6. Some medical and other data should be collected from everyone on a routine basis. This raises issues, particularly regarding DNA and other matters that are “fearful.” Blood oxygen levels might raise less of an issue, but certainly could be of concern because it would constitute a “crack in the dike.”

7. An enhanced search engine design may create problems in patent practice outside the traditional patent search by altering issues of prior art and obviousness. The question is does a vast data base of integral “parts” and processes mean that things become obvious that hither to were not? Will this alter the “obviousness” standards?

8. The use of ideas and facts through comprehensive and relational search may affect copyright issues relative to fair use, derivative rights, the end result of which does not presently ameliorate the risk and costs of defending a legal action. This is an integral component of the paradox requiring differentiation among rules for the collection of necessary data, access to the data and the right to use the data without liability.

9. Human health related issues require different standards than simple commercial or non-critical matters. A method of assessment and authorization for the collection of such data needs to be determined. Rules should be crafted to account for the significant difference in the treatment of data based on overriding public interest and health safety and welfare concerns when considering the exclusionary limitations of private property rights.

10. Ambiguities in the use of apparent facts, ideas and related concepts should be resolved in favor of the user if good faith and in selected areas of public welfare.

11. Transaction costs need to be reduced as a barrier to innovation both in terms of intellectual property generally and specifically as regards public welfare issues. This requires examination of mechanism to determine controversies by motion practice, by administrative panel, or assessing costs differentially to the winners and losers.

Conclusion (or just the beginning?)

As stated at the outset, this is a project conceived fully exploratory to satisfy a nagging curiosity concerning the power of the internet search engine and intellectual property regimes. The initial objective was to provide “food for thought” in a study that will continue for the near future both as regards autism and the fundamentals of intellectual property that affect creative endeavors. The object of this presentation has been to inform and solicit thoughts and commentary regarding casual factors affecting autism, as well as express concerns about the future of intellectual development that may

depend on access to and use of published materials as contemplated by the granting of property rights under the Constitution.