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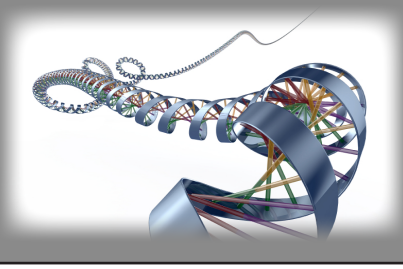

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Overview of the Genetic Information Nondiscrimination Act

The Genetic Information Nondiscrimination Act of 2008 (GINA) affects most businesses with employment-related duties, as well as subcategories of companies in a few niches. In certain contexts, GINA prohibits use of "Genetic Information" which is defined as "information about [an] individual's genetic tests, the genetic tests of family members of [the] individual, and the manifestation of a disease or disorder in family members of [the] individual."

First the aspect which has the broadest effect, in employment. GINA makes it an unlawful employment practice for an employer to fail or refuse to hire, or to discharge, any employee, or otherwise to discriminate against any employee with respect to the compensation, terms, conditions, or privileges of employment of the employee, because of genetic information with respect to the employee. GINA also makes it unlawful to limit, segregate, or classify the employees of the employer in any way that would deprive or tend to deprive any employee of employment opportunities or otherwise adversely affect the status of the employee as an employee.

Lastly, GINA makes it unlawful to request, require, or purchase genetic information with respect to an employee. There are some exceptions, such as if it is given inadvertently in a medical history provided by the employee or if used for genetic services in a wellness program and the employee provides written authorization. Only the employee and a licensed healthcare professional have the genetic information, and any such information is used only for purposes of the wellness program. Requesting information so the employer can comply with the certification in the Family and Medical Leave Act or similar state laws is not unlawful.

Additionally, it is not unlawful if the information is purchased in commercially available documents, but not medical databases or court records or if used for genetic monitoring of the biological effects of toxic substances required under federal or state law. Lastly, it is not unlawful if the information is needed by forensic or other laboratories doing DNA analysis for law enforcement purposes, but only to the extent the information is needed to detect sample contamination.

Similar prohibitions also apply to employment agencies, labor organizations, joint labor management committee controlling apprenticeship or other training. There are a number of remedies and penalties provided which are akin to those in other federal anti-discrimination laws.

The sections affecting narrower groups relate mostly to health insurance decisions. Section 101 prohibits a health insurance issuer from using genetic information to adjust the premium or contribution amounts for a group. It also prohibits use of genetic information for any underwriting purposes including making rules for or determination of eligibility for benefits under a plan, application of any pre-existing conditions, or other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits. Section 102 also prohibits use of such information in individual health care policies, while Section 104 prohibits MediGap insurers from using genetic information in decisions on pricing or eligibility of such insurance. There are also strict privacy and confidentiality provisions in Section 105.

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GINA does not prevent, however, use of information about manifestation of a disease in an individual in setting health care premiums. [Note: it is unlawful to collect this information about the individual's family members.] In this context it is important to explain the difference between genetic information and "manifestation of a disease in the individual." The simplest way to put this is that the traits of the individual's inheritance to cause disorders potentially are off-limits but the actual occurrence for these traits to occur is fair game. A more precise way of defining some genetic information is that which is contained in a "Genetic Test" which is an "analysis of human DNA, RNA, chromosomes, proteins, or metabolites, that detects genotypes, mutations or chromosomal changes." A genetic test does not include analysis of proteins or metabolites which are "directly related to a manifested disease, disorder, or pathological condition that could be reasonably detected by a health care professional with appropriate training and expertise in the field of medicine involved." (Section 101) It is reasonable to expect there will be significant difficulty sorting out what constitutes genetic information or manifestation of a disease in the individual. Biology is not so neat that the lines between genetic information and manifestation are so clear.

U.S. Patent And Trademark Office Agrees To Cooperate With Foreign Offices In Examination

On October 31, 2008, representatives of the U.S. Patent and Trademark Office met with representatives from four major foreign intellectual property offices to state their intentions to increase cooperation in the examination of patents. The other offices represented were from Europe, Japan, Korea, and China.

The five offices issued a statement that they desire to reduce the duplication in work that occurs when applications are submitted in more than one country for patent protection. This practice has become very common as a result of the Patent Cooperation Treaty, which provides a streamlined (if expensive) procedure for submitting the same application in many countries. It is common for inventors in the U.S. to also seek protection in the major markets of Europe and Japan, as well as in our NAFTA partners Canada and Mexico. Inventors less commonly apply for protection overseas in large countries with uncertain levels of patent protection, such as India, China, Brazil, and the Eurasian countries of the former Soviet Union.

The five offices hope to develop a system by which the results of examination of an application in any given office can be easily accessed and evaluated by the other offices. The U.S. Patent and Trademark Office believes this will help to reduce its massive backlog of unexamined cases. Although no substantive procedures were agreed upon, the five offices decided to explore ways to standardize examination, such that the examination process in each office would be almost identical to the processes in the others. To this end the five offices agreed on ten "Foundation Projects" to explore prior to their next planned meeting in 2009.

The most important aspects of the plan are to be determined by China. China will implement common rules for examination and quality control, and they will implement a system of statistical analysis to evaluate the performances of each of the offices under the new system. It is unclear how the new rules for examination will affect the long-established examination procedures at the U.S. Patent and Trademark Office, much of which is based on U.S. law.

The European Patent Office will assemble a grand database of prior art literature that all offices will use in conducting searches during examination. The EPO will also draft a patent classification system to be used by all offices. If properly executed, this new database and classification system could add a tremendous level of predictability to the examination process.

Japan will develop a common application format to be used in all participating countries which is to be electronically implemented. Japan will also develop a method by which each office can access search and examination results from other offices, and gain access to applications. This project will do the most to eliminate redundancy in examination of applications. One relevant unanswered question is whether applications marked for non-publication in the U.S. will be accessible to foreign patent offices.

Korea will develop standard approaches to training patent examiners, and develop methods of mechanical language translation. The latter will be established with the goal of allowing prior art to be used by all offices regardless of the original language in which the prior-art document was written. The U.S. Patent and Trademark Office currently relies on live translators for this task. Considering the current state of mechanical translation, this project will be of dubious value to the effort as a whole.

The U.S. Patent and Trademark Office will develop a common approach to sharing search strategies between the offices. This will allow an examiner in a given office to understand and evaluate a prior search executed by an examiner in a different office. The U.S. is also responsible for developing "common search and examination support tools." It is not readily clear to what this refers, but it probably refers to the development of search software that is amenable to sharing search results between offices.

Overall, the proposed plan should have advantages for applications that are filed in more than one of the offices

involved. If implemented, the plan will create some uncertainty in terms of how U.S. examination standards will be changed to conform.

PTO Announces New Work-Sharing Initiatives

The United States Patent and Trademark Office (the "PTO") is inundated with unexamined patent applications. This so called "patent backlog" is currently 760,000 applications currently and is expected to increase to over 1,300,000 applications by 2011. Directives implemented by the PTO to reduce this backlog, such as hiring 6,000 new patent examiners over the next five years, have been criticized as insufficient to address the problem. The PTO has recently acknowledged that it cannot "hire its way out of the backlog" and is now focused on slowing the growth of the backlog instead of reducing it. The PTO has specifically cited the complexity and number of the biotechnology and pharmaceutical applications as key reasons the backlog exists. In fact, the "average" biotechnological or pharmaceutical application waits approximately two (2) years for a first response from the PTO (i.e., the First Office Action on the Merits) and issues about three (3) years after filing. Applicants have a vested interest in accelerating prosecution without trading the degree of protection a patent can offer as patent term is calculated from the filing date of a patent rather than issuance date.

In an effort to slow the growth of the backlog (and presumptively speed up prosecution), the PTO has promulgated new rules concerning the filing of divisional and continuation applications and attempts to limit the number of claims filed in patent applications, although the implementation of those rules has been enjoined by the courts. The PTO has also implemented "work-sharing initiatives" with foreign patent offices to slow the growth of the backlog. One of the initiatives is the Patent Prosecution Highway ("PPH"). Of those initiatives, the PPH is the most advanced and mature process.

The original PPH pilot program was implemented in conjunction with the Japan Patent Office ("JPO") in July 2006 and both offices heralded the program as a success. In 2007, the PPH program was expanded to include the Australian and U.K Intellectual Property Offices and most recently the European Patent Office. The PPH program was established to enable an applicant whose claim(s) are determined to be allowable/patentable in the Office of First Filing ("OFF") to have a corresponding application filed in the Office of Second Filing ("OSF") advanced out of turn for examination while at the same time allowing the OSF to exploit the search and examination results of the OFF.

There are several requirements an application must meet before it can request participation in the PPH program. First, the U.S. application must be either a Paris Convention Application, a national stage application under the Patent Cooperation Treaty ("PCT") or a so-called by-pass application filed under 35 U.S.C. § 111(a). Certain applications are excluded from participation, including provisional, plant, design, and re-issue applications as well as re-examination proceedings and applications subject to secrecy orders. If an applicant is requesting that an U.S. application be advanced out of turn for examination when the PTO is the OSF, at least one claim must be determined to be allowable/patentable by the OFF (i.e., the JPO). Next, all claims in each U.S. application for which a request for participation in the PPH program is filed must "sufficiently correspond" or be amended to "sufficiently correspond" to allowable patent claims in the OFF. Claims "sufficiently correspond" when the claims are of the same or similar scope, excluding differences due to claim format requirements in each office. Further, the U.S. application must not have entered prosecution.

To request participation in the PPH program, the applicant must file a request for participation and a petition to make the application special under the PPH program. The applicant must submit a copy of all office actions for each filing in the OFF containing the allowable/patentable claims that are the basis for the request or request that the PTO obtain a copy of such documents from the OFF. The applicant must submit an Information Disclosure Statement ("IDS") listing the documents cited by the examiner of the OFF in that prosecution. The applicant must also submit copies of all the documents cited in the IDS except U.S. patent or U.S. patent applicant publications. Finally, a request for participation in the pilot program and special status granted in an application will not carry over to any continuing or divisional applications arising from the parent application. Continuing applications must separately fulfill the conditions set forth above. If an application is accepted for admission into the PPH program, the U.S. application will be taken up for examination by the U.S. examiner before all other categories of applications, except those clearly and conditionally for allowance, those with set time limits and those that have been previously granted special status for accelerated examination.

The overarching goal of the PPH program was to allow an applicant to "fast track" prosecution in the OSF when the OFF finds one or more claims allowable in the corresponding application. The OSF benefits from the search and examination results from the OFF before conducting its own examination, therefore, the applicant gets the results faster and with higher quality. Although the PPH program is relatively new, the patent examining core approves of the changes thus far. Some empirical observations by U.S. examiners include the narrower claim sets than in a typical US case and fewer claims. Fewer claims equals

faster processing and the examiners have a better base of the prior art from which to start their searches. Further, the field of search by the examiners is narrowed. It is yet to be determined whether patents granted through the PPH program are as valuable as those granted through normal prosecution, as patents issued through the PPH will be narrower in scope than patents issued through the normal process. Further, the litigation issues, such as patent prosecution estoppel could be broadened under the PPH program as arguments made in seeking allowance in the OFF could be used in litigation to narrow the scope and breadth of patent claims.

As of January 1, 2009, Bradley Arant Rose & White LLP and Nashville's well-respected Boult, Cummings, Conners & Berry PLC will merge to form Bradley Arant Boult Cummings LLP. Our new firm will have more than 350 attorneys in seven offices strategically located in Tennessee, Alabama, Mississippi, North Carolina and the District of Columbia. Together, we will offer you or your clients a talented legal team with not only expanded areas of service and enhanced industry knowledge, but also the continued dedication to excellence in client service you have come to expect from our firms.

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