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Inherent Anticipation in Biotechnology Patents in Light of In Re Cruciferous Sprout Litigation and Elan Pharmaceuticals

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INHERENT ANTICIPATION IN BIOTECHNOLOGY PATENTS IN LIGHT OF *IN RE CRUCIFEROUS SPROUT LITIGATION* AND *ELAN PHARMACEUTICALS*

By
Brian Orr

INTRODUCTION

Before a company invests in developing new technologies or new products that would infringe patents held by others, the company must decide whether to attempt to acquire a license or to risk litigation.[1] If a company decides to purchase a patent license, the company will greatly reduce its chances of exposure to litigation.[2] However, this security comes at a cost, and not all patent holders are willing to license their patents. On the other hand, if a company decides not to take a license, the company risks the possibility of a patent infringement lawsuit. If judgment is found against the company, not only will damages likely result, but an injunction may be granted, and the company may lose its entire investment.

Companies need to make a cost-benefit-risk analysis when determining whether or not to take a license. This is especially true in the pharmaceutical industry. A recent study by the Federal Trade Commission determined that from 1998-2000 generic drug manufacturers sought to enter the market with a new generic version of a patented drug before the patent expired approximately 20 percent of the time.[3] This is an increase of 18 percent from the 1980's.[4] If a patent is believed to be invalid, companies are more likely to decide not to take a license. By establishing more definable standards for determining whether a patent is anticipated, companies can more readily determine if a patent is in fact invalid. Therefore, by establishing more definable standards for determining

whether a patent is anticipated, companies can more capably decide whether to invest in a license or risk litigation.

Recently, the United States Court of Appeals for the Federal Circuit has examined inherency in two biotech cases.[5] In *In re Cruciferous Sprout Litigation*, the court found that certain properties of food products were inherent and, therefore, anticipated.[6] On the other hand, in *Elan Pharmaceuticals, Inc. v. Mayo Foundation*, the Federal Circuit found that there was no inherency when a prior patent gave only general instructions for gene transfers between humans and animals.[7] In light of the recent *In re Cruciferous Sprout Litigation* and *Elan Pharmaceuticals* decisions, the biotechnology industry is in need of a clearer standard for inherency.

This note will examine the *In re Cruciferous Sprout Litigation* and *Elan Pharmaceuticals* decisions and determine the impact they will have on the ability of inventors to obtain valid biotech patents. Part I will give a general background of inherency in patent law. Part II will outline the *In re Cruciferous Sprout Litigation* and the *Elan Pharmaceuticals* opinions. Part III will contain a list of factors that should be helpful in determining if an element is inherent in a prior art reference for biotech patents. Finally, Part IV will apply the factors to the facts in *In re Cruciferous Sprout Litigation* and *Elan Pharmaceuticals.*

I. BACKGROUND OF INHERENCY

A. Patents Generally

Patents grant inventors of eligible inventions the right to exclude others from making, using, selling, offering to sell or importing the patented invention.[8] After the

patent term has expired, the invention enters into the public domain, and is available to the public.

The Constitution grants Congress the authority to create a patent system, if Congress so desires.[9] Congress has used its authority to create the 1952 Patent Act, which provides the guidelines for the current U.S. patent law.[10]

B. Overview of Anticipation

Under the current patent statute, in order to obtain a patent, an invention must be new, or in other words, novel.[11] A patent can lack novelty if any of the circumstances contained in 35 U.S.C. § 102 are fulfilled.[12] Commonly, a patent lacks novelty if the invention claimed was in public use or on sale in the U.S. one year prior to the date the patent application was filed, if the invention was known or used by others in the U.S. before the invention was conceived, or if the invention was described in a printed publication in any country one year prior to the date the patent application was filed.[13] If an invention is not novel, it is considered anticipated.[14]

For an invention to be anticipated, each and every element of the invention must be found in a single prior art reference.[15] A prior art reference is anything from the past or present that is known and available to the public.[16] The prior art reference must enable one skilled in the art to make the claimed invention.[17] Although the prior art reference must contain each and every element of the invention, the elements may be either express or inherent.[10] An element is expressly disclosed if the prior art reference directly states the element. An element is inherently disclosed if one skilled in the art could infer the element. To prove inherency, additional sources apart from the prior art reference can be used to demonstrate that one skilled in the art would have known the inherent element.[18]

If all the elements are either inherently or expressly found in a single prior art reference, the patent is considered anticipated and invalid.

C. Policy Reasons for Inherency

The patent system encourages innovation, and novelty discourages inventive activity that will not enrich the public knowledge.[19] Novelty balances the interests of the public and the inventor.[20] Novelty requires an inventor to secure his patent promptly and only rewards the inventor with patent protection if he seeks such protection early.[21] This encourages an inventor to file for a patent as soon as possible, which in turn enriches the public knowledge.[22]

Inherent anticipation serves two policy goals: First, it assures that patents do not become too large with excessive details. An inventor may choose not to disclose all of the information in a prior art reference, assuming that the omitted details were inherent and one skilled in the art would inherently know what was not disclosed. However, it is not necessary that one skilled in the art appreciate the inherent disclosure at the time the prior art reference was made public.[23] Therefore, a second policy goal also exists.

Secondly, inherent anticipation coincides with the notion that an inventor should only be granted patent protection for his development to the extent it advances public knowledge.[24] If certain information has already been disclosed to the public inherently, an inventor should not be granted patent protection for that information.

II. *IN RE CRUCIFEROUS SPROUT LITIGATION* AND *ELAN PHARMACEUTICALS, INC. V. MAYO FOUNDATION*

A. *In re Cruciferous Sprout Litigation*

Johns Hopkins University owned three patents that described a method for growing and preparing certain sprouts.[25] Particular spouts that are harvested at a specific time contain higher levels of glucosinolate.[26] Foods with high levels of glucosinolates produce Phase 2 enzymes in the human body; these enzymes help detoxify carcinogens, thus reducing the risk of developing cancer.[27] Johns Hopkins licensed the patents to Brassica Protection Products, LCC; Brassica then sued Sunrise Farms and others for patent infringement.[28] As a defense, Sunrise Farms claimed that the patents were anticipated.[29]

The court agreed with Sunrise Farms and invalidated the patents.[30] Numerous prior art references identified the sprouts as edible.[31] Although these prior art references did not mention glucosinolates or the potential of the sprouts to induce Phase 2 enzymes,[32] the court determined that high levels of gluscosinolates were present in sprouts as long as sprouts have existed.[33] Therefore, the gluconsinolates were inherent characteristics disclosed by the prior references.[34] The court concluded that because the patents merely recognized a property inherently disclosed in prior art references, the patents were anticipated.[35]

B. *Elan Pharmaceuticals, Inc. v. Mayo Foundation*

a. Facts

The prior art reference applied in this case was a patent granted to Dr. Michael Mullan concerning transgenic mice.[36] Transgenic mice are created by combining mouse DNA with mutated human genes.[37] These transgenic mice were developed so that the mice would be susceptible to Alzheimer's disease.[38] The Mullan Patent disclosed various procedures for making such transgenic mice.[39] However, Mullan did not produce any

transgenic mice or determine which of the procedures would be effective in the production of the mice.[40]

Meanwhile, the Elan Patent described a procedure for the production of transgenic mice, which are created by combining mouse DNA with a mutated human gene known as the "Swedish mutation."[41] The "Swedish mutation" gene has an extremely high incidence of early-onset Alzheimer's disease.[42] It is believed that the presence of a protein fragment called beta-amyloid peptide (betaAP) in the brain induces Alzheimer's disease.[43] It is understood that betaAP is formed by the separation of a protein produced in the brain, called amyloid precursor protein (APP).[44] In turn, the APP protein is split into a protein fragment called amino terminal fragment (ATF-betaAPP), and an enzyme.[45] The ATF-betaAPP protein fragment is larger and therefore easier to detect than the betaAP molecule.[46] Not all mice will accept the "Swedish mutation" gene, but those that do will have detectable levels of ATF-betaAPP in their brains.[47] The Elan Patent only included mice with the presence of detectable levels of ATF-betaAPP.[48]

b. The Federal Circuit's Holding

Mayo argued that the Mullan Patent inherently disclosed transgenic mice with detectable levels of ATF-betaAPP because under the Mullan Patent some percentage of the transgenic mice produced would have been expected to produce detectable levels of ATF-betaAPP.[49] The court disagreed, determining that the Mullan patent was merely general instructions to transfer genes between humans and animals.[50] The court held that such general instructions did not anticipate the second patent and offered no more than a starting point for further experimentation.[51]

c. Judge Dyk's Dissenting Opinion

Judge Dyk dissented from the majority opinion.[52] Judge Dyk asserted that the Mullan Patent included transgenic mice having the Swedish mutation form of APP, and that a mouse containing APP would produce a detectable amount of ATF-betaAPP.[53] Although only a small amount of the transgenic mice produced under the Mullan Patent would express the Swedish form of the APP, all the mice that did contain the APP would produce ATF-betaAPP.[54] Judge Dyk reasoned that the Mullan Patent therefore anticipated the Elan Patent, and that the Elan Patent should be declared invalid.[55]

III. FACTORS FOR BIOTECH PATENTS

The doctrine of inherent anticipation applies in three basic circumstances:[56] The first situation occurs when the prior art reference describes an inherent property.[57] The second occurs when the prior art reference contains an inherent use.[58] The third incident occurs when the prior art reference contains an inherent method of practicing the art.[59] Since each of these circumstances requires different determinations of whether a patent has been anticipated, this article has developed separate factors for inherent properties, inherent uses and inherent methods.

A. Inherent Properties

A patent can be anticipated if a prior art reference contains the same properties. The prior art reference need not expressly describe every property; instead, these properties may be inherently disclosed.[60] The cases, *Schering Corp. v. Geneva Pharmaceutical, Inc.* and *In re Omeprazole Patent Litigation*, demonstrate how anticipation of inherent properties applies to the biotech industry.

1. *Schering Corp. v. Geneva Pharm., Inc.*

In February 1984, Schering Corporation filed and was granted a patent (the '233 Patent) for the drug loratadine, which is used to treat allergic reactions.[61] When humans ingest loratadine, DesCarboethoxylLoratadine (DCL) is produced.[62] However, at the time the application was filed, one skilled in the art would not have realized that the ingestion of loratadine would produce DCL.[63] Later, Schering and Geneva Pharmaceuticals performed clinical studies that demonstrated that DCL is produced when loratadine is ingested.[64] Subsequently, Schering also obtained a separate patent (the '716 Patent) for DCL.[65]

The court determined that although the '233 Patent did not expressly describe DCL, the '233 Patent still anticipated the '716 Patent because DCL is an inherent function of the '233 Patent.[66] The court stated that "the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer."[67] The court concluded that, although artisans of ordinary skill in the art did not recognize the inherent function of DCL, the production of DCL after the ingestion of loratadine is an inherent function of the use of loratadine, and therefore the '716 Patent was anticipated by the '233 Patent.[68]

2. *In re Omeprazole Patent Litigation*

In 1981, Astra was granted a patent (the '431 Patent) for the chemical compound omeprazole, which Astra sells under the name Prilosec™.[69] Scientists at Astra later determined that when omeprazole is administered to humans it produces sulphenamides, which inhibit the enzymes responsible for gastric-acid secretion in the stomach lining.[70]

In 1987, Astra was granted a patent (the '499 Patent) for sulphenamide compounds and the administration of sulphenamide.[71]

When the '431 Patent expired in October of 2001, Genpharm and Chemior desired to sell generic versions of omeprazole.[72] Astra claimed that since the ingestion of omeprazole causes sulphenamides to form in the body, Genpharm and Chemior's proposed plan to manufacture omeprazole would infringe the '499 Patent.[73]

The court determined that the '499 Patent was an attempt to patent "a scientific explanation for the prior art's function," which is unpatentable.[74] The court held that the prior art reference inherently anticipated any claim for the production of sulphenamides formed after the ingestion of omeprazole.[75]

3. Summary and Factors for Inherent Properties

In both *Schering Corp.* and *In re Omeprazole* drug companies attempted to patent later discoveries from previously-held patents. If the inherent properties of the previous patents were allowed to be patented, this would result in the extension of the original patent's monopoly.

To prevent inherent properties from being patented, the factors the courts should take into consideration in determining whether a prior art reference inherently anticipates a subsequent claimed invention are:

(1) whether the inherent property was known when the prior art reference was published;

(2) whether the inherent property is always produced;

(3) whether the prior art reference gives the public the benefit of the inherent property that the patent is attempting to claim.

Starting with the first factor -- whether the inherent property was known when the prior art reference was published -- strengthens a claim of anticipation. If the inherent property was known at the time the prior art reference was published, this would indicate that one skilled in the art could infer the inherent property. On the other hand, the patent holder in both *Schering Corp.* and *In re Omeprazole* did not know that their respective drugs produced a specific result when ingested by humans.[76] However, when the companies later discovered and tried to patent the specific results, those patents were found to be anticipated and invalid.[77] Therefore, a patent can still be anticipated if the inherent property was not known when the prior art reference was published because the knowledge of one skilled in the art may have increased since the prior art reference was published.

Turning to the second factor, if the inherent property is not always produced following the instructions of the prior art reference, this decreases the possibility that one skilled in the art would discover the inherent property in the prior art reference, weakening a claim of anticipation.

Additionally, possibilities or probabilities are not enough; the inherent property must be certain to occur from the information disclosed in the prior art reference. On the other hand, a claim is stronger if the inherent property is always produced. Under these circumstances, one skilled in the art would be more likely to discover the inherent property and attribute the inherent property to the prior art reference.

Finally, if, prior to the filing of a patent application, a prior art reference already disclosed the inherent property to the public, the public will not be enriched by the patent application. The U. S. patent system essentially grants inventors a monopoly in exchange

for publicly disclosing how to produce their invention. On the other hand, if the inherent property has not been previously made known to the public, the inventor has disclosed something new to the public and, in turn, should be granted a patent. Yet, if the public already knows of the inherent property, the new patent has not revealed anything to the public and the inventor should not be granted a patent.

B. Inherent Uses

A patent can also be anticipated if the prior art reference contains an inherent use. Since artisans may not disclose every use for an invention, a use may be inherent in a prior art reference.[78] The following cases, *MEHL/Biophile Int. Corp. v. Milgraum* and *In re Woodruff*, establish how the anticipation of inherent uses relates to patent law.

1. *MEH/Biophile Int. Corp. v. Milgraum*

MEHL/Biophile held a process patent for the removal of hair using a Q-switched laser.[79] MEHL/Biophile claimed that Milgraum and others infringed their patent, while Milgraum contended that MEHL/Biophile's patent was anticipated.[80] Milgraum relied upon two prior art references in claiming anticipation - a manual for the RD-1200 laser that described the removal of tattoos using a Q-switched laser, and the Polla article which described using a Q-switched laser to remove hair from guinea pigs.[81]

The court concluded that the RD-1200 manual did not anticipate the patent because it did not teach all the claim limitations.[82] Since the RD-1200 manual dealt with the removal of tattoos, the manual did not discuss aligning the laser over hair follicles.[83] The court noted that although the manual did not discuss the removal of hair, it was possible that a person following the manual could align the laser over a hair follicle.[84]

However, the court determined that such an "occasional result" was not inherent, and the manual did not anticipate the patent.[85]

The court reached a different result with the Polla Article. The court concluded that the Polla Article inherently taught the vertical alignment of a Q-switched laser over a hair follicle, finding the difference between the removal of human hair and guinea pig hair irrelevant to the anticipation analysis.[86] Also irrelevant was the fact that the Polla Article did not discuss the removal of hair as a goal of the study.[87] These findings led the court to hold that the Polla Article anticipated MEHL/Biophile's patent.[88]

2. *In re Woodruff*

Woodruff filed a patent application that described a process to prevent the growth of fungi on fresh fruits and vegetables by modifying the atmosphere.[89] Both the Patent and Trademark Office and the Board of Appeals rejected the application, and Woodruff appealed.[90] In rejecting Woodruff's patent application, the Board of Appeals relied upon a sole prior art reference, a U.S. Patent issued to McGill.[91] The McGill patent disclosed a process to maintain the fresh appearance of leafy and head vegetables stored over an extended period of time.[92] The McGill Patent was designed to prevent bacterial growth and discoloration, but the McGill Patent made no mention about the growth of fungi.[93] Both the Woodruff and McGill storage methods used a modified atmosphere and a lower temperature.[94]

The court determined that one of the purposes of the McGill Patent, preventing discoloration, would inherently include fungal growth.[95] Therefore, the court concluded that the McGill patent contained the "new use" that Woodruff desired to patent.[96]

3. Summary and Factors for Inherent Uses

The plaintiffs in both *MEHL/Biophile* and *In re Woodruff* wanted to patent a process or a compound based upon the development of a new use for the process or compound. Inventors may be granted a method patent for the development of a new use. However, a process or a compound patent generally has a greater scope of protection than method patents, and so should only be granted in limited circumstances.

In determining if a process or compound patent is warranted, the courts should analyze:

(1) whether all the same steps are used in the prior art reference;

(2) whether the use only occasionally results from the steps disclosed in the prior art reference.

Beginning with the first factor, if all the same steps are used in both the prior art reference and the later filed patent, only a method patent should be granted for a non-previously disclosed use. In *MEHL/Biophile*, both the patent and the prior art reference discussing hair removal of guinea pigs contained the same steps to use a laser to remove hair.[97] Similarly, in *In re Woodruff*, the same process for storing vegetables by modifying the atmosphere and lowering the temperature was used in both the prior art reference and the patent.[98] Both the patents in *MEHL/Biophile* and *In re Woodruff* were found invalid although an inherent use for the processes explained in the prior art references was later developed.[99] Alternatively, if the prior art reference and the patent contain different steps to achieve a different use, this would indicate that the patent is not anticipated.

Addressing the second factor, if the use described in the patent only occasionally results from the process disclosed in the prior art reference, the patent should not be

anticipated. The *MEHL/Biophile* court found the possibility of hair being removed by accidentally aligning a laser over a hair follicle during the removal of a tattoo was an occasional result.[100] An undiscovered, occasional result does not enrich the public knowledge.[101] If a subsequent inventor discovers an occasional result and discloses this information through a patent, this would weaken a claim of anticipation. Alternatively, if the use disclosed in the patent always occurs under the process described in the prior art reference, the patent would not enrich the public knowledge, and claim of anticipation would be strengthened.

C. Inherent Methods

Finally, a claim can be anticipated if it discloses a substantially similar method to the method claimed in the prior art reference. Even if the prior art reference does not explicitly state the same method, a method can still be inherent.[102] The following cases, *In re Baxter Travenol Labs*, *Glaxo, Inc. v. Novopharm Ltd.*, and *Glaxo Wellcome, Inc. v. Ben Venue Laboratory, Inc.*, demonstrate how the anticipation of inherent methods applies to the biotech industry.

1. *In re Baxter Travenol Labs*

Baxter filed a patent application for an invention for the collecting, processing, and storing of blood using a multiple-blood-bag system.[103] The invention used the first bag for the collection and storage of red blood cells and at least one additional bag for the collection and storage of another blood component.[104] The first bag was made of the plastic polymer di-2-ethylmexyl phithalate (DEHP), while the second bag was made of a different plastic.[105]

In October 1969 a Baxter employee wrote a prior art reference, "Contract PH 43-67-1403; Final Technical Progress Report; Development of Containers for Preservation of Frozen Blood Components."[106] This document described a new blood-bag system that used a bag made of polyvinyl chloride (PVC) as the donor bag and a secondary bag made of Teflon.[107] The document described the blood-bag system as very similar to another blood container manufactured by Baxter at that time.[108] The document did not expressly refer to the use of DEHP, but at the time the prior document was written, all of the blood-bag systems Baxter manufactured contained DEHP.[109]

Because the prior document referred to a blood-collection system manufactured by Baxter and the systems manufactured by Baxter contained primary bags comprised of DEHP, the court determined that one skilled in the art would have known that the similar blood-collection system referred to contained a primary bag consisting of DEHP.[110] Therefore, the court concluded that the patent application was anticipated.[111]

2. *Glaxo, Inc. v. Novopharm Ltd.*

In July 1977, Glaxo filed a patent application that described a method for the production of ranitidine hydrochloride (Form 1).[112] For three years after the filing of the patent, Glaxo experimented with the production of ranitidine hydrochloride using procedures not disclosed in the 1977 patent.[113] In April 1980, using one of the new procedures, Glaxo produced a new form of ranitidine hydrochloride (Form 2).[114] In 1981, Glaxo filed a patent for Form 2 in the United States.[115]

Novopharm sought to invalidate Glaxo's 1981 patent by claiming it was anticipated by the 1977 Glaxo patent.[116] Novopharm argued that Form 2 was inherent in the patent filed in 1977.[117] Novopharm followed the 1977 patent to manufacture ranitidine hydrochloride, but made some minor changes to the procedure.[118] However, these changes were not outside the teachings of the 1977 patent for one skilled in the art, and the court found these changes acceptable.[119]

The court then determined that the method for production of ranitidine hydrochloride disclosed in the 1977 patent sometimes produced Form 1 and sometimes produced Form 2.[120] Therefore, the procedures for making ranitidine hydrochloride in the 1977 patent did not invariably result in the production of Form 2.[121] Because possibilities or probabilities cannot establish inherency, the court concluded that Novopharm failed to prove inherency.[122]

3. *Glaxo Wellcome, Inc. v. Ben Venue Laboratory, Inc.*

Glaxo developed an intravenous, injectable version of the drug Zantac™, which is used to treat ulcers.[123] Glaxo filed for and was granted a patent (the '658 Patent) for the intravenous form of Zantac™.[124] The patent described the process for manufacturing

Zantac™ using a pH level between 5.0 and 6.0.[125] A pH level between 5.0 and 6.0 increased the chemical stability of Zantac™, which in turn increased the shelf life of the drug.[126] Glaxo continued to study the chemical stability of Zantac™, and later determined that Zantac™ was most stable at a pH of 7.0.[127] In 1984, Glaxo filed a patent for intravenous Zantac™ manufactured at a pH of 7.0.[128] Initially, the Patent and Trademark Office rejected the patent application as being both anticipated and obvious, but upon reconsideration, the patent (the '790 Patent) was granted.[129]

The '658 Patent did not expressly state a pH level of 7.0.[130] Therefore, to prove anticipation Ben Venue had to show that one skilled in the art would realize that a pH of 7.0 was inherent.[131] The '658 Patent did teach that the pH level affects chemical stability, but the court concluded this disclosure was merely a starting point for further experimentation.[132] Determining that one skilled in the art using the '658 Patent would not have recognized that the chemical stability of injectable Zantac™ could be increased when a pH level of 7.0 was used, the court concluded that the '658 Patent did not inherently anticipate the '790 Patent.[133]

4. Summary and Factors for Inherent Methods

In the cases discussed above, the plaintiffs wanted to patent a process that was at least partially disclosed in a prior art reference.

In determining what constitutes an inherent method courts should analyze:

(1) what the industry or corporate standard was at the time the prior art reference was published;

(2) whether the process disclosed in the prior art reference always produces the result sought to be patented;

(3) whether the amount of experimentation required to discover the subsequent inherent method was "undue."

Beginning with the first factor, determining what the industry or corporate standard was at the time the prior art reference was published, helps clarify the knowledge of one skilled in the art. In, *In re Baxter Travenol Labs*, all bags manufactured by Baxter at the time the prior art reference was published were made of the same material.[134] Baxter later filed a patent claiming a bag made of that material, and the *In re Baxter Travenol Labs* court held that the patent was anticipated by the prior art reference.[135] One skilled in the art would have known of the industry or corporate standard, even if the standard were not disclosed in the prior art reference. Therefore, if the inherent method was the industry or corporate standard at the time the prior art reference was published, this would indicate that one skilled in the art would have known of the inherent method, and a claim of anticipation would be strengthened. Even if the industry or corporate standard were not the inherent method, this would not necessarily weaken a claim of anticipation if the knowledge of one skilled in the art has increased since the publication of the prior art reference.

Turning to the second factor, a claim of anticipation may be strengthened or weakened by the consistency of the results of the prior art reference. Consistent results increase the chance that the one skilled in the art would have discovered the inherent method and already disclosed the inherent method to the public, strengthening a claim of anticipation. Alternatively, occasional results like those in *Glaxo, Inc. v. Novopharm*[136] are not enough to show that one skilled in the art would discover the inherent property from the prior art reference, weakening a claim of anticipation.

Addressing the final factor -- the amount of subsequent experimentation required to discover an inherent method -- would indicate inherency of the method in the prior art reference. If an undue amount of experimentation were required to develop the inherent method, the public did not previously know of the inherent method, and the inventor should be granted a patent. In *Glaxo Wellcome, Inc. v. Ben Venue Laboratory, Inc.*, Glaxo developed a more stable version of a drug that was outside the teachings of the prior art reference.[137] The *Glaxo Wellcome* court found that the prior art reference was merely a starting point for further experimentation, and the prior art reference did not anticipate the patent.[138] Like the prior art reference in *Glaxo Wellcome*, if an undue amount of experimentation were required to develop the inherent method, this would weaken a claim of anticipation.

IV. APPLICATION OF FACTORS

Applying the factors put forth in this note to the facts in, *In re Cruciferous Sprout Litigation* and *Elan Pharmaceuticals* will help illustrate how the factors will give a clearer standard for inherent anticipation. Since inherency is a question of fact, the trier of fact should apply these factors.

A. Application of the Factors to *In re Cruciferous Sprout Litigation*

In, *In re Cruciferous Sprout Litigation* an inherent property was claimed to be anticipated. Like the drugs in *Schering Corp. v. Geneva Pharmaceuticals* and *In re Omeprazole Patent Litigation*, the patent in, *In re Cruciferous Sprout Litigation* claimed a property of the sprouts that was inherent in the sprouts themselves. Because an inherent property was claimed to be anticipated, the factors for inherent properties should be applied. These factors include: (1) whether the inherent property was known when the

prior art reference was published; (2) whether the inherent property is always produced; and (3) whether the prior art reference gives the public the benefit of the inherent property that the patent is attempting claim.

The prior art references in, *In re Cruciferous Sprout Litigation* identified the sprouts claimed in the patent as edible.[139] These prior art references did not disclose the beneficial effects of the glucosinolates contained in the sprouts;[140] therefore, the inherent property of the production of Phase 2 enzymes from the ingestion of the glucosinolates in the sprouts was not known when the prior art references were published. Since the inherent property was not known, this factor would weigh against a finding of inherent anticipation.

Sprouts have contained glucosinolates as long as sprouts have existed.[141] Although certain types of sprouts contain higher levels of glucosinolates,[142] when the sprouts with higher levels of glucosinolates are consumed, Phase 2 enzymes are always produced in the human body. Therefore, the inherent property of the production of Phase 2 enzymes from the ingestion of the glucosinolates in the sprouts is always produced when the sprouts listed in the patents are grown and eaten. Because the inherent property is always produced, this factor would weigh in favor of a finding of inherent anticipation.

The prior art references in, *In re Cruciferous Sprout Litigation* did not explain that certain varieties of sprouts contain glucosinolates, which produce Phase 2 enzymes, which, in turn, reduces the risk of developing cancer.[143] However, by following the prior art references, one skilled in the art would be able to reduce the risk of developing cancer by cultivating and consuming the certain types of sprouts listed in the patents at issue. Therefore, the public already had the benefit of the inherent property that the patent was

attempting to claim, and this factor will weigh in favor of a finding of inherent anticipation.

After applying the facts from *In re Cruciferous Sprout Litigation*, two of the three factors weigh in favor of finding inherent anticipation. Therefore, the patents in, *In re Cruciferous Sprout Litigation* should be considered anticipated by the prior art references and held invalid. The Federal Circuit reached the same conclusion.[144]

B. Application of the Factors to *Elan Pharmaceuticals*

Rather than an inherent property, an inherent method was claimed to be anticipated in *Elan Pharmaceuticals.* Like the prior art references in *In re Baxter Travenol Labs*, *Glaxo, Inc. v. Novopharm Ltd.*, and *Glaxo Wellcome, Inc. v. Ben Venue Lab. Inc.,* the process disclosed in the patent in *Elan Pharmaceuticals* was at least partially disclosed in a prior art reference. Because an inherent method was claimed to be anticipated, the factors for inherent methods should be applied. These factors include: (1) what the industry or corporate standard was at the time the prior art reference was published; (2) whether the process disclosed in the prior art reference always produces the result sought to be patented; and (3) whether the amount of experimentation required to discover the subsequent method was "undue."

No transgenic mice were produced using the prior art reference, the Mullan Patent.[145] Since no mice were produced, no industry or corporate standard for the production of transgenic mice would have existed when the Mullan Patent was published. Therefore, what the industry or corporate standard was at the time the prior art reference was published would not apply.

The methods for producing transgenic mice disclosed in the Mullan Patent were unpredictable and had low success rates.[146] However, under the Elan Patent, the mice are screened for detectable levels of ATF-betaAPP.[147] This screening determines whether the Swedish DNA has been transferred to the mice, and in turn whether the mice will produce Alzheimer's disease.[148] Unlike the Elan Patent, the process disclosed in the Mullan Patent does not always produce the results sought to be patented. Therefore, this factor would weigh in against a finding of inherent anticipation.

The Mullan Patent described methods for making transgenic mice, but did not disclose the production of transgenic mice having detectable levels of ATF-betaAPP.[149] When the Mullan Patent was filed, no one (1) had made a transgenic mouse that contained the Swedish gene; (2) knew whether the Swedish gene would be accepted by mouse DNA; or (3) knew whether levels of ATF-betaAPP would be detectable in mice.[150] Given the amount of experimentation required, after the Mullan Patent, to produce transgenic mice with detectable levels of ATF-betaAPP, the amount of experimentation required to discover the subsequent method should be considered "undue." Therefore, this factor should weigh against a finding of anticipation.

After applying the facts from *Elan Pharmaceutical* to the factors put forth in this note, two of the three factors weigh against a finding of inherent anticipation. Therefore, the patents in *Elan Pharmaceutical* should not be considered anticipated by the prior art reference and held not invalid. The vacated Federal Circuit decision reached the same conclusion.[151]

CONCLUSION

The factors put forth in this note give legal practitioners and the biotechnology industry a clearer standard for inherency. Applying the factors to relevant cases will help lawyers and judges better determine whether a patent has been inherently anticipated. Additionally, the factors will allow businesses to more readily determine whether a patent is invalid, and in turn, help businesses decide whether to acquire a license or risk litigation.

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[1] *See* DEBORAH A. SOMERVILLE ET AL., THE BIOTECH PATENT: TO LICENSE OR LITIGATE? 1 (2002) (Discussing factors that biotech companies should take into account when deciding whether to take a license or risk infringement).

[2] Litigation can still result if the company exceeds the scope of the license.

[3] FEDERAL TRADE COMMISSION, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY ii (2002), *available at* http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

[4] *See id.* During the 1980's, generic drug manufactures sought to manufacture new generic drugs before the patents expired only 2 percent of the time. *Id.*

[5] *See* Elan Pharm., Inc. v. Mayo Found. for Med. Edu. & Research, 304 F.3d 1221 (Fed. Cir. 2002), *vacating as moot*, 2002 U.S. App. LEXIS 26092 (Fed. Cir. Dec. 18, 2002); *see* In re Cruciferous Sprout Litig., 301 F.3d 1343 (Fed. Cir. 2002).

[6] In re Cruciferous, 301 F.3d at 1352.

[7] Elan Pharm., 304 F.3d at 1229. The Federal Circuit *Elan Pharmaceuticals* decision was recently vacated pending rehearing of the case *en banc*. *See* Elan Pharm., Inc. v. Mayo Found., 2002 U.S. App. LEXIS 26092, *1 (Fed. Cir. Dec. 18, 2002).

[8] *See* 35 U.S.C. § 271(a) (2000).

[9] *See* U.S. CONST. art. I, § 8, cl. 8. "The Congress shall have the power … to promote the progress of science and the useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries." *Id.*

[10] *See generally*, 35 U.S.C. §§ 1-476 (2000).

[11] 35 U.S.C. § 101 (2000). "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title." *Id.*

[12] *See* 35 U.S.C. § 102 (2000).

[13] *See* 35 U.S.C. § 102(a) (2000); *see* 35 U.S.C. § 102(b) (2000). A patent is invalid based on lack of novelty under 35 U.S.C. §102(a) if before the applicant conceived of the invention, the invention was known or used by used by others in this country or was patented or disclosed in a publication worldwide. 35 U.S.C. § 102(a). A patent is also invalid based on lack of novelty under 35 U.S.C. §102(b) if prior

to one year before the patent was filed, the invention claimed was in public use or on sale in this country. 35 U.S.C. § 102(b).

[14] *See* Lewmar Marine, Inc. v. Barient, Inc., 827 F.2d 744, 748 (Fed. Cir. 1987). Discussing the change in the definition of anticipation after the 1952 Patent Act from both novelty and obviousness to just novelty. *Id.*

[15] *See* Constant v. Advanced Micro-Devices, Inc., 848 F.2d 1560, 1570 (Fed. Cir. 1988). "A claim is anticipated if each every element *as set forth in the claim* is found, either expressly or inherently described, in a single prior art reference." *Id.*

[16] *See* Akim F. Czmus, *Biotechnology Protection in Japan, the European Community, and the United States*, 8 TEMP. INT'L & COMP. L.J. 435, 439 (1994).

[17] PPG Indus., Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 1566 (Fed. Cir. 1996).

[10] In re Robertson, 169 F.3d 743, 745 (Fed. Cir. 1999).

[18] *See* 1 IVER P. COOPER, BIOTECHNOLOGY AND THE LAW §4:2 (2002). The extrinsic evidence can be used only to explain, but not expand, the meaning of the prior art reference. *Id.*

[19] *See* 1 CHISUM ON PATENTS § 3.01 (2002). "Novelty deters people from engaging in original inventive activity that will not in fact increase 'the store of common knowledge.'" *Id.* (quoting Dewey v. Almy Chem. Co. v. Mimex Co., 124 F.2d 986, 989 (2nd Cir. 1942)).

[20] *See* Gould, Inc. v. United States, 579 F.2d 571, 580 (Ct. Cl. 1978).

[21] *See id.*

[22] *See id.*

[23] *See* MEHL/Biophile Int'l. Corp. v. Milgraum, 192 F.3d 1362, 1366 (Fed. Cir. 1999).

[24] *See* In re Schoenwald, 964 F.2d 1122, 1123 (Fed. Cir. 1992).

[25] In re Cruciferous Sprout Litig., 301 F.3d at 1345.

[26] *Id.*

[27] *Id.*

[28] *Id.* at 1345-46.

[29] *Id.*

[30] *Id.* at 1352.

[31] *Id.* at 1351. These references included: STEPHEN FACCIOLA, CORNUCOPIA: A SOURCE BOOK OF EDIBLE PLANTS 47 (1990), and ESTHER MUNROE, SPROUTS TO GROW AND EAT 9-14 (1974). *Id.*

[32] *Id.* at 1349.

[33] *Id.* at 1350.

[34] *Id.*

[35] *Id.* at 1352. Not all products that exist in nature will anticipate patents. *See* PHILIPPE G. DUCOR, PATENTING THE RECOMBNANT PRODUCTS OF BIOTECHNOLOGY AND OTHER MOLECULES 12 (1998); *see* KENNETH J. BURCHFIEL, BIOTECHNOLOGY AND THE FEDERAL CIRCUIT 65-66 (1995). A purer form of a compound or composition that occurs in nature will generally be considered novel, because the purer compound or composition will have a different molecular composition. *See id; see id.* at 65. Additionally, claims for naturally existing products have been determined novel when the claimed products have increased activity, distinguishing physical characteristics, or distinguishing physical form. *See* BURCHFIEL, *supra* note 33, at 66.

[36] Elan Pharm., Inc. v. Mayo Found., 304 F.3d 1221, 1224-25 (Fed. Cir. 2002).

[37] *See id.* at 1223-24.

[38] *Id.* at 1223-24.
[39] *Id.* at 1224-26.
[40] *Id.* at 1226.
[41] *Id.* at 1224.
[42] *Id.*
[43] *Id.*
[44] *Id.*
[45] *Id.*
[46] *See id.* at 1226.
[47] *See id.*
[48] *Id.* at 1226-27.
[49] *See id.* at 1228.
[50] *Id.* at 1228.
[51] *Id.* at 1229.
[52] *Id.* at 1231.
[53] *See id.* at 1234-35.
[54] *Id.* at 1235.
[55] *See id.*
[56] *See* Steven C. Carlson, *Inherent Anticipation*, 40 IDEA 297, 306 (2000); *see also* Bradford J. Duft & Eric P. Mirabel, *Principles of Inherency*, 77 J. PAT. & TRADEMARK OFF. SOC'Y 539, 543 (1995).
[57] *Id.*
[58] *Id.*
[59] *Id.*
[60] *See* Carlson, *supra* note 40, at 307.
[61] Schering Corp. v. Geneva Pharm., Inc., 2002 U.S. Dist. LEXIS 14587, *9 (D.N.J Aug. 8, 2002). Loratadine is used to treat allergic reactions. *Id.* at *4.
[62] *Id.*
[63] *Id.*
[64] *Id.* at **9-11.
[65] *Id.* at *4.
[66] *See id.* at *22.
[67] *Id.* at *22-23.
[68] *Id.* at *25.
[69] *In re Omeprazole Patent Litigation,* 2001 U.S. Dist. LEXIS 7103, *1, *7 (S.D.N.Y. 2001).
[70] *Id.* at *8, *25.
[71] *Id.* at *8.
[72] *Id.* at *1, 4.
[73] *Id.* at *8.
[74] *Id.* at *36 (quoting Atlas Powder Co. v. IRECO, Inc., 190 F.3d 1342, 1347 (Fed. Cir. 1999)).
[75] *Id.* at **37-38. Generic drug companies have had great success in patent infringement cases; generic drug companies have prevailed over brand number companies in approximately 73 percent of the cases. *See* FEDERAL TRADE COMMISSION, *supra* note 3, at 13.
[76] *See Schering Corp.*, 2002 U.S. Dist. LEXIS at *9; *see In re Omeprazole*, 2001 U.S. Dist. LEXIS at *25.
[77] *See Schering Corp.*, 2002 U.S. Dist. LEXIS at *26; *see In re Omeprazole*, 2001 U.S. Dist. LEXIS at *38.
[78] *See* Carlson, *supra* note 40, at 314-15.
[79] MEHL/Biophile Int'l. Corp. v. Milgraum, 192 F.3d 1362, 1364 (Fed. Cir. 1999).
[80] *Id.* at 1363,

[81] *Id.* at 1364.
[82] *Id.* at 1365.
[83] *Id.*
[84] *Id.*
[85] *Id.*
[86] *Id.*
[87] *Id.*
[88] *Id.* at 1367.
[89] In re Woodruff, 919 F.2d 1575, 1575 (Fed. Cir. 1990). The atmosphere required a lower amount of oxygen and a greater amount of carbon monoxide than ordinary air. *Id.*
[90] *Id.*
[91] *Id.*
[92] *Id.* at 1576.
[93] *Id.*
[94] *Id.*
[95] *See id.* at 1577.
[96] *Id.* at 1578.
[97] *See MEHL/Biophile*, 192 F.3d at 1366-67.
[98] *See In re Woodruff*, 919 F.2d at 1577-78.
[99] *See MEHL/Biophile*, 192 F.3d at 1367; *see In re Woodruff*, 919 F.2d at 1578.
[100] *See id.*
[101] *See* 1 CHISUM ON PATENTS, *supra* note 19, § 3.03. "A true accident gives no assurance that the same result can be reached by others at a later time." *Id.*
[102] *See* Carlson, *supra* note 28, at 310.
[103] In re Baxter Travenol Labs, 952 F.2d 388, 389 (Fed. Cir. 1991).
[104] *Id.*
[105] *Id.*
[106] *Id.* at 390.
[107] *Id.*
[108] *Id.*
[109] *Id.*
[110] *Id.*
[111] *Id.* at 391.
[112] *Glaxo Inc. v. Novopharm Ltd, 830 F. Supp. 871, 873*
[113] *Id.*
[114] *Id.*
[115] *Id.* at 874.
[116] *Id.* at 873.
[117] *Id.* at 874.
[118] *Id.* at 876. These changes included warming the mixture and slightly increasing the pH. *Id.*
[119] *Id.*
[120] *Id.* at 877.
[121] *Id.*
[122] *Id.*
[123] Glaxo Wellcome, Inc. v. Ben Venue Lab., Inc., 1998 U.S. Dist. LEXIS 19774, *4-5 (N.D. Ohio 1998). The injectable form of the drug can be used for unconscious patents or patents that are incapable of swallowing. *Id.* at *5.
[124] *Id.* at *5.
[125] *Id.* at *6.
[126] *Id.*

[127] *Id.* at *8.
[128] *Id.*
[129] *Id.* at *9.
[130] *Id.* at *22.
[131] *Id.* at *24.
[132] *See id.*
[133] *Id.* at *25.
[134] *See In re Baxter Travenol Labs*, 952 F.2d at 390.
[135] *See id.* at 389, 392.
[136] *See Glaxo, Inc. v. Novopharm*, 830 F. Supp. at 877.
[137] *See Glaxo Wellcome, Inc. v. Ben Venue Lab., Inc.*, 1998 U.S. Dist. LEXIS at *8.
[138] *See id.* at *25.
[139] *See In re Cruciferous Sprout Litig.*, 301 F.3d at 1351. The court listed examples of the prior art references including: STEPHEN FACCIOLA, CORNUCOPIA: A SOURCE BOOK OF EDIBLE PLANTS 47 (1990), and ESTHER MUNRONE, SPROUTS TO GROW AND EAT 9-14 (1974). *Id.*
[140] *Id.*
[141] *See id.* at 1350. The court commented that glucosinolates and their Phase 2 enzyme producing effects of sprouts have existed as long as sprouts themselves, which was clearly more than one year prior to the filing of the patents at issue. *Id.*
[142] *See id.* at 1345. The patents at issue recognized that certain types of sprouts contained far greater concentrations of glucosionlates. *Id.*
[143] *Id.* at 1349.
[144] *See id.* at 1352. The Federal Circuit held that the patents were anticipated by the prior art and therefore invalid. *Id.*
[145] Elan Pharmaceuticals, Inc. v. Mayo Foundation, 304 F.3d 1221, 1226 (Fed. Cir. 2002).
[146] *See id.* "Expert witnesses for both sides testified as to the difficulty, uncertainty, unpredictability, and low success rate of each method that has been used to create transgenic animals." *Id.*
[147] *Id.* at 1229.
[148] *Id.*
[149] *Id.* at 1228.
[150] *Id.* at 1230.
[151] *See id.* at 1229. Prior to vacating the decision pending a rehearing en-banc, the Federal Circuit held that the patents were not anticipated by the prior art and reversed the summary judgment of invalidity granted by the district court. *Id.*