MUST STR PRIMER SEQUENCES BE DISCLOSED OR PUBLISHED?

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LAW V SCIENCE

In October of 2000, at the 11th International Symposium on Human Identification, I gave a presentation on the admissibility of STR DNA typing in criminal cases. An abstract of this presentation was published in the Proceedings for that symposium. Two years later, at least in Minnesota, the admissibility of STR DNA typing is still undecided. On Nov. 5, 2002, however, two cases were argued before the Minnesota Supreme Court. Hopefully, the court's decision will settle the STR admissibility issue once and for all. The purpose of this article is to trace what has occurred since the first Minnesota Frye[1]/admissibility hearing was held in January of 2000, and to examine what has become the major claim that STR typing results should be excluded: that the failure of the manufacturers of STR typing kits to reveal and/or publish the primer sequences for the loci used in the typing kits precludes admissibility because without knowledge of the primer sequences, the scientific community cannot determine the accuracy and validity of the STR typing kits.

MINNESOTA COURTS AND GENETIC TESTING

That Minnesota appellate courts are still wrestling with this issue is no surprise to anyone familiar with the admissibility battles which have played out in Minnesota courts. The history of forensic testing of body fluids in Minnesota is a history punctuated with strange rulings, going all the way back to the days of electrophoretic testing of proteins and enzymes. In State v Kim, 398 NW2d 544, (Minn. 1987), the Minnesota Supreme Court ruled that while the results of electrophoretic testing were admissible, the jury could not be given the combined probability statistic or random match probability for all of the tests. Instead, the jury could only be told that none of the tests excluded the defendant, and the percentage of the population which possessed each of the particular types of the protein or enzyme in question. Thus, if the defendant matched the evidence sample at six different tests, the jury could only be told the percentage of the population which possessed each of those individual genetic markers, not the percentage of the population possessing that combination of markers. Interestingly, post-trial interviews revealed that jurors routinely multiplied the percentages together to come up with their own combined percentage. Most often this led to the jury using a figure actually less favorable to the defendant than the actual combined figure, as no correction factors were applied. Thus the effort of the Minnesota Supreme Court to "protect" the defendant not only failed to protect him, it actually resulted in prejudice to the defendant.

Though challenged in State v Schwartz, 447 NW2d 422, (Minn. 1989), Minnesota's first DNA appellate decision, this rule remained in effect until 1994. In State v Bloom, 516 NW2d 159 (Minn. 1994), the court ruled that if calculated according to the ceiling principle as described in NRC I (DNA Technology in Forensic Science, 1992), a combined probability statistic could be presented to the jury. This perhaps was the result of a threat by the state legislature to pass a constitutional amendment giving the legislature the authority to govern the procedural aspects of criminal proceedings, including questions concerning the admissibility of evidence.

ADMISSIBILITY: BY WHAT STANDARDS ?

Unlike what occurred in many jurisdictions, no significant DNA admissibility cases were decided by Minnesota appellate courts after the 1994 decision in Bloom, supra. Though PCR testing using the DQ Alpha + PM, and D1S80 kits became common in Minnesota criminal cases, no defendant ever claimed he was wrongly convicted because PCR testing results were introduced at his trial. In a number of other

[1] Frye v United States, 293 F. 1013, 1014 (D.C. Cir. 1923)

states, DNA typing using the PCR methodology had received favorable rulings in the appellate courts. Because there was no comparable decision in Minnesota, the admissibility hearing included testimony about not just STR typing specifically, but about the PCR methodology in general.

In 1993, the United States Supreme Court in the case of Daubert v Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993) broke from the long established test for the admissibility of scientific evidence established in Frye.[1] This decision established the test for admissibility in federal courts to be a relevancy test. Will the testing assist the trier of fact to understand or determine a fact in issue ? Since that decision, admissibility in all federal courts and an increasing number of state courts has been decided according to this relevancy test. However, Minnesota and a number of other states retain the Frye test for admissibility. Stated simply, this test is that the results of scientific testing are not admissible unless there is general acceptance in the particular field in which the scientific principle belongs. To this "general acceptance" test, many states, including Minnesota, have added a "second prong": the evidence must have a foundation that is scientifically reliable.

DEFENSE TACTICS IN THE "DNA WARS"

In addition to contesting whether PCR/STR DNA typing has achieved "general acceptance" and whether it is foundationally reliable, an important tactic used by the defense has been to demand voluminous discovery. In the days of RFLP and early PCR kits admissibility hearings, the defense demanded virtually every piece of paper produced by the lab and/or the maker of the probes, kits, etc. Since the beginning of the STR admissibility hearings, the focus has turned to primer sequences and the raw data produced by the developer during the initial validation studies. It is important to note that there are two claims here: the broader claim is that without the primer sequences, it is impossible for the scientific community to determine the validity of the claimed accuracy of the testing process, and therefore, general acceptance cannot occur, and, secondly, that it is a violation of the discovery rules to refuse to provide the primer sequences.

IS THIS REALLY A DISCOVERY ISSUE ?

The "need to know" or discover information about, in this case, a testing methodology exists in both the criminal justice system and the scientific community. In the criminal justice system, the issue here is how much information about the testing methodology is needed by the defense so that they and their experts have a fair opportunity to determine whether or not the test in general produces accurate and reliable results, and as to this case, whether those presumably valid methods were properly applied so that the results are accurate and reliable. In the setting of the scientific community, the "need to know" or discover information about a testing methodology is determined by whether or not other scientists need to know any particular piece of information in order to make an independent judgment of the validity of the testing method or, in this case, the particular testing kits.
Criminal discovery rules create (in many states) an obligation on the part of both the prosecution and defense to broadly provide documents or other information pertinent to the issues in the case. The purpose of criminal discovery is to prevent what was once referred to as "trial by ambush", and to allow each side the opportunity to prepare and meet evidence produced by the other side. The object of the system is to seek the truth, and there is good reason to believe that broad discovery will promote this goal. Discovery under the rule is only to the other party. Therefore, it would seem that if information were provided in any form, even under a "protective order", that this would comply with the discovery rules. Although the maker of the STR typing kits which are the most widely used in the forensic community, Applied Biosystems, at first refused to provide the primers even under a protective order, that initial policy was changed in late 1999. As a result, during the early months of 2000, the primer sequences were provided to experts for either party, on the condition that they sign a protective order. This being the case, there seems to be little merit to the claim that a claim of discovery violation should be upheld, and the test results excluded for that reason.

PCR/STR TYPING ADMISSIBILITY: CURRENT STATE OF THE LAW

A review of decisions from other jurisdictions reveals that for PCR kits, including kits which type other than STR loci have received favorable rulings in approximately 55 decisions in state and federal courts. These include decisions from at least 26 state appellate courts and 2 circuit courts of appeal. In terms of the admissibility of typing results derived from the STR multiplex typing kits in question in Minnesota, the Profiler Plus and CoFiler kits, there are at least eight decisions from the appellate courts of other states. All of these decisions favor admissibility. None of these decisions decide the issue of whether or not primer sequences must be widely disclosed or published.

THE SUGGESTED RATIONALE FOR PRIMER DISCLOSURE/PUBLICATION

Those who claim that the primers must be disclosed argue that the failure to do so means that DNA test results derived from STR kits cannot be received in court. It goes without saying that if accurate and reliable, DNA evidence can be extremely probative, informative evidence on the question of guilt or innocence. The suppression of evidence probative of the ultimate question is not something which should be lightly ordered by a court of law. Again, the ultimate goal of the justice system is to find the truth. Suppression of probative evidence, unless it furthers a very important policy goal, should be a last resort. The opponents of admissibility offer two rationales for exclusion: first, that the standards and controls set by the scientific community itself (the TWGDAM guidelines) require broad disclosure/publication, and second, that without the primers, the scientific community is unable to verify the reliability and accuracy of the methodology.

TWGDAM Guidelines or DAB Standards: Which Controls ?

In 1988, a group of 31 experts in DNA typing, mostly DNA lab directors, both public and private, developed a set of guidelines offered as appropriate for guiding DNA testing labs. In State v Schwartz, 447 N.W.2d 422, 428 (Minn. 1989), the Minnesota Supreme Court ruled that the TWGDAM (Technical Working Group on DNA Analysis Methods) guidelines were the “standards and controls” that DNA typing labs should follow to establish reliability of the results. Those guidelines were amended in 1991 and 1995 to reflect changes and advances in the technology. Congress passed the DNA Identification Act of 1994, and in it provided for the formation of a national DNA Advisory Board (DAB). This board, made up of experts in science, ethics, and the law was to, among other things, promulgate a set of standards for DNA testing labs. Congress, as well as many experts, believed that standardization of testing methods and practices was an important goal in the effort to ensure accuracy and reliability of results. The act provided that until such standards were arrived at and adopted, the TWGDAM guidelines would remain in effect. On October 1, 1998, as a result of this Act of Congress, the DAB standards superceded the TWGDAM guidelines. The TWGDAM committee remained in existence during this period, and in fact drafted the DAB standards which the DAB later approved and sent to the Director of the FBI for final approval. TWGDAM has since changed its name to SWGDAM (Scientific Working Group on DNA Analysis Methods).

All of this is important because while both the TWGDAM guidelines and the DAB standards refer to “primer sequences”, the TWGDAM guidelines contain a section not found in the DAB standards. TWGDAM 4.4.1.1 provides that “The primers must be of known sequence.” The defense claim is that this section means that the primers must be widely disclosed/published. The defense further claims that in Minnesota, because of the specific reference to the TWGDAM guidelines in two early decisions of the Minnesota Supreme Court, the TWGDAM guidelines control, not the DAB standards.

There are a number of problems with this position. First of all, it is apparent that in referring to the TWGDAM guidelines in its early decisions, the supreme court was not making judgments about the value or necessity of specific provisions of the TWGDAM guidelines. Rather, the supreme court was, as it should, looking to the scientific community for guidance as to what the scientific community believed were the necessary standards and controls to best ensure accuracy and reliability of test results. The supreme court has long recognized that lawyers and judges have no business making value judgments about the efficacy of scientific methods and procedures.

Secondly, the testimony of two of the experts called by the state made it clear that there was no truth to the defense claim that these were two separate and distinct sets of guidelines/standards, and that the TWGDAM guidelines still had validity. Dr. Bruce Budowle, the head of the FBI DNA testing program, former chairman of TWGDAM and member of the DAB testified that after the DAB was formed, the TWGDAM committee drafted and sent to the DAB what eventually became the DAB standards. Thus, as he testified, even if the DAB had never been formed, what today are known as the DAB standards would have become the latest revision of the TWGDAM guidelines, just as the 1991 and 1995 amended guidelines had become at those times the latest revision of the guidelines. Dr. Fred Bieber, associate Professor of Pathology at Harvard University and a member of the DAB testified that what eventually became the DAB standards were in fact drafted by TWGDAM and were adopted by the DAB with little or no change. After being sent to the FBI director for his approval, they became effective after his approval again without any change.

Thirdly, that the phrase "primers must be of known sequence" does not mean disclosed/published in a broad manner. Rather it was understood by the TWGDAM committee to mean that the primers must be known to the maker and must remain stable, so that users could be sure that the product they were working with had not in any way been changed, even if that change might arguably be beneficial. Dr. Budowle testified that this phrase was inserted in the 1991 TWGDAM guidelines, and that for years after that, TWGDAM members received, validated, and put into use several DNA typing kits which used primers the sequence of which are still not known to anyone other than the manufacturer. TWGDAM members could hardly have intended to put into effect a requirement which would have invalidated the very kits they were using.

Thus it appears that the claim that disclosure/publication is required by the standards and controls governing DNA typing labs, the TWGDAM guidelines, is without any merit.

CAN THE PCR/STR TYPING KITS IN QUESTION BECOME GENERALLY ACCEPTED WITHOUT THE PRIMER SEQUENCES ?

Three witnesses called by the defense in the admissibility hearings in Minnesota testified that it was their opinion that the primer sequences ought to be disclosed. Two of them did so on the basis that the TWGDAM guidelines, in their opinion, required disclosure. The third witness was the only one to offer specific reasons why the primers were needed by him, as well as the scientific community at large. Among the reasons he offered were:

Knowing the primers would allow him to search DNA sequence data bases to determine if the primers recognized the correct loci;
Knowing the primers would allow him to determine thermal stability;
Knowing them would allow him to determine if all 28 primers are compatible;
Knowing them would help determine if they would fold up on themselves;
Knowing them would allow a determination of whether they are complementary, i.e., would they fold up on themselves
Science is a controlled study, without them, the experiments cannot be produced;

Finally, he testified that no reviewer should accept for publication any article about STR testing which does not reveal the primers.

A critical examination of the claimed inability of the scientific community as a whole reach general acceptance as to this methodology and these kits reveals a number of reasons to question the validity of this claim.

1. Years of "practice" in the scientific community appears to rebut this idea. As Dr. Budowle testified, there are a number of kits which became widely used and relied upon not just in the United States but world wide, yet the primers for those kits are still not known.
2. Somewhere on the order of 100 papers have been published in a variety of scientific journals specifically referring to these STR typing kits (Profiler Plus and CoFiler) yet the authors, reviewers, and editors of those journals do not know the sequences;
3. The scientific community determines reliability and accuracy by empirical testing, not by referring to a formula written on a piece of paper. The scientific community has taken these

kits into their laboratories, used them under a variety of conditions, to type a wide variance of biological samples, and apparently unanimously determined the kits work as claimed;

4. While wide usage alone perhaps would not be conclusory evidence of general acceptance, the fact that these kits are used by somewhere between 80 and 90 percent of the forensic labs world wide is strong evidence of the view of the scientific community;
5. Not a single published article, court case, or study identifies this as an issue or concern. Several examples are illustrative. In 1996, a second lengthy study on the issue of DNA forensic testing was published by the National Research Council, The Evaluation of Forensic DNA Evidence, or NRC II. There is no mention of the primer sequence issue in that comprehensive report. Attorney General Janet Reno appointed a blue ribbon panel called The National Commission on the Future of DNA Evidence in 1998. A report entitled The Future of Forensic DNA Testing: Predictions of the Research and Development Working Group was published in November of 2000. Although this report concludes that STR typing is likely to be the methodology of choice for the next ten years, there is not a single mention of the primer sequnce issue in that report. Yet the primers for numerous STR multiplex typing kits were and are still considered proprietary. Finally, Reference Guide on DNA Evidence, pp. 485-578, in the Reference Manual on Scientific Evidence, written by two members of NRC II, there is no mention of the primer sequence as an issue.
6. Finally, in the most recent hearing, two of the three defense experts who two years ago testified that they did not believe that enough work had been done to validate these kits testified in May of 2002 that the kits have now been validated and shown to accurately and reliably type single source DNA samples, as well as some mixtures;

THE TRIAL COURT'S VIEW OF THE PRIMER SEQUENCE ISSUE

After the first Frye hearing, Judge Thor Anderson ruled that the defense had suffered no harm from not having the primers. The Minnesota BCA (the testing lab) has validated, as have many other labs. "The system is like a Model A Ford. Thousands of owners can tell us it works even if Henry Ford can't or won't explain it. The customers have validated this system." Feb. 15, 2000 State v Dishmon, File # 99047345.

In the first criminal case to reach the appellate court, a panel of the Minnesota Court of Appeals ruled that Judge Anderson had erred in ruling STR typing admissible, as earlier decisions of the Minnesota Supreme Court adopted provisions of the concededly superceded TWGDAM guidelines. However, the conviction was not reversed, as the court ruled the admissibility of the DNA evidence was harmless error.

As a result of this court of appeals opinion, State v Traylor, C6-01-244, a new Frye hearing was commenced. In a written opinion by the Honorable Thor Anderson, the same judge who wrote the Feb. 15, 2000 opinion Judge Anderson suppressed the results of DNA typing in 8 cases, at least 3 of which are homicides. He did so very reluctantly. He wrote: "DAB and TWGDAM have both been complied with, but there is one ambiguous issue; What does "'The PCR primers must be of known sequence' mean…..Is the issue what these words mean to the Court; or what the words mean to the scientific community and the people who drafted them ?…..this court is bound by the higher court's ruling…….the system is astoundingly accurate, virtually foolproof. The dilemma is that the scientific community has abandoned the TWGDAM guidelines….Like the American pre-constitutional Articles of Confederacy…….The necessity of deciding this case in this way is an unmitigated tragedy…it is used by reputable labs all over the world…..Notwithstanding all of this, this Court is a court of law, and as such its duty is to sacrifice common sense as a burnt offering on the altar of guidelines rejected even by their creators."

IS THIS A RED HERRING OF THE MOST OBVIOUS KIND ?

Perhaps the issue can be stated this way; "Can a scientific methodology clearly generally accepted in the scientific community be excluded as evidence in the legal system because the primer sequences (something not deemed necessary to a determination of accuracy and reliability by the scientific community) were not disclosed/published ?"

The legal system requires that the methodology be generally accepted. The scientific community determines the utility of a methodology by whether it is validated. No scientists speak in terms of "general acceptance." This is the parlance of lawyers and judges. However, validation in the scientific community is the functional equivalent of general acceptance in the legal system. Since validation has unquestionably occurred in the scientific community, it follows that the primers are not required. Since courts defer to the scientific community on validation issues, then it must follow that revealing the primers is not required by the scientific community.

An appellate court in Minnesota accepted the specious argument that knowing the primer sequences is essential to a determination of accuracy and validity of the methodology by the scientific community. Hopefully, the Minnesota Supreme Court will recognize, for all the reasons stated in this article that this is simply not true, and that the effort to exclude PCR/STR typing on this basis is a red herring of the first degree.